AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 84 Monday,
No. 42 March 4, 2019

Pages 7261–7792

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 84 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–512–1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Printed on recycled paper.

Contents

Federal Register

Vol. 84, No. 42

Monday, March 4, 2019

Agency for Healthcare Research and Quality
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 7370–7372

Agriculture Department
See Animal and Plant Health Inspection Service

Animal and Plant Health Inspection Service
PROPOSED RULES
Domestic Quarantine Regulations:
Pale Cyst Nematode, 7304–7306
NOTICES
Environmental Impact Statements; Availability, etc.:
Predator Damage Management in Idaho, 7326

Centers for Disease Control and Prevention
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 7372–7379

Centers for Medicare & Medicaid Services
PROPOSED RULES
Medicare and Medicaid Programs:
Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers, 7610–7680

Coast Guard
RULES
Removal of Regulated Navigation Areas, Safety Zones, Security Zones, and Special Local Regulations within District 7, 7285–7288
Safety Zone:
Chicago Harbor, Navy Pier Southeast, Chicago, IL, 7290–7292
Cumberland River, KY, 7288–7290
Security Zone
Corpus Christi Ship Channel, Corpus Christi, TX, 7292–7294
PROPOSED RULES
Special Local Regulation:
Bush River and Otter Point Creek, Harford County, MD, 7310–7313

Commerce Department
See International Trade Administration
See National Institute of Standards and Technology
See National Oceanic and Atmospheric Administration

Community Living Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
American Indian, Alaskan Natives and Native Hawaiian Programs, 7379–7381

Comptroller of the Currency
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Interagency Appraisal Complaint Form, 7415–7417

Defense Department
See Navy Department

Education Department
RULES
Program Regulations Superseded by Reauthorizations of the Perkins Act, 7294–7299
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Submission to the Office of Management and Budget for Review and approval; Comment Request; Federal Student Aid Feedback System, 7348–7349
Performance of Accrediting Agencies, 7349–7350

Employment and Training Administration
NOTICES
Selection Procedures for Reviewing Applications Filed by Employers Seeking Temporary Employment of H–2B Foreign Workers in the United States, 7399–7403

Energy Department
See Federal Energy Regulatory Commission
NOTICES
Meetings:
Environmental Management Site-Specific Advisory Board Chairs, 7351
Methane Hydrate Advisory Committee, 7350–7351

Environmental Protection Agency
RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
Massachusetts; Air Emissions Inventory, Emissions Statements, Source Registration, and Emergency Episode Planning Provisions, 7299–7301
National Emission Standards for Hazardous Air Pollutants:
Surface Coating of Wood Building Products Residual Risk and Technology Review, 7682–7712
PROPOSED RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
Kentucky: Jefferson County Process Operations, 7313–7315
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
New Source Performance Standards for Petroleum Dry Cleaners (Renewal), 7365–7366
Broadly Applicable Alternative Test Methods, 7363–7365
Clean Air Act Prevention of Significant Deterioration Permit Issued to Tucson Electric Power for the Irvington Generating Station Project, 7366

Export-Import Bank
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 7366–7367

Federal Aviation Administration
RULES
Airworthiness Directives:
Dassault Aviation Airplanes, 7269–7271
Fokker Services B.V. Airplanes, 7261–7264
Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.) Airplanes, 7272–7274
The Boeing Company Airplanes, 7264–7269
Amendment of Class D Airspace and Class E Airspace:
Schenectady, NY, Ithaca, NY, and Albany, NY, 7274
PROPOSED RULES
Amendment of Class E Airspace:
Dickinson, ND, 7306–7308
Removal of Area Navigation (RNAV) Route Q–106:
Southern United States, 7308–7309
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Landing Area Proposal, 7412–7413

Federal Communications Commission
PROPOSED RULES
Truth in Caller ID, 7315–7323
NOTICES
Meetings:
Technological Advisory Council, 7367

Federal Emergency Management Agency
NOTICES
Meetings:
Board of Visitors for the National Fire Academy, 7397

Federal Energy Regulatory Commission
RULES
Interlocking Officers and Directors; Requirements for Applicants and Holders, 7274–7283
PROPOSED RULES
Mergers or Consolidations by a Public Utility; Correction, 7309–7310
NOTICES
Application:
Georgia Power Co., 7354–7356
Kaukauna Utilities, 7359–7360
Combined Filings, 7351–7354, 7356–7357, 7359, 7361–7362
Complaint:
Independent Market Monitor for PJM v. PJM Interconnection, LLC, 7357
Environmental Impact Statements; Availability, etc.:
Turlock Irrigation District, Modesto Irrigation District; Meeting, 7357
Filing:
Cooperative Energy, 7351
Prairie Power, Inc., 7352
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
Citigroup Commodities Canada ULC, 7359
Meetings:
Reliability Technical Conference, 7353
Qualifying Conduit Hydropower Facility:
City and County of Denver, Colorado, 7358
Coleman Hydro LLC, 7360–7361
Request under Blanket Authorization:
Spire Storage West, LLC, 7362–7363

Federal Reserve System
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 7367–7369
Changes in Bank Control:
Acquisitions of Shares of a Bank or Bank Holding Company, 7369

Federal Trade Commission
NOTICES
Revised Jurisdictional Thresholds for Section 7A of the Clayton Act, 7369–7370
Revised Jurisdictional Thresholds for Section 8 of the Clayton Act, 7369

Fish and Wildlife Service
NOTICES
Endangered and Threatened Species:
Receipt of Recovery Permit Applications, 7398–7399

Food and Drug Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records, 7381–7383
Financial Disclosure by Clinical Investigators, 7388–7390
Guidance:
Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under the Federal Food, Drug, and Cosmetic Act, 7390–7391
List of Bulk Drug Substances for Which There Is a Clinical Need Under the Federal Food, Drug, and Cosmetic Act, 7383–7388

Health and Human Services Department
See Agency for Healthcare Research and Quality
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Community Living Administration
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration
RULES
Compliance with Statutory Program Integrity Requirements, 7714–7791
PROPOSED RULES
21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 7424–7610
Medicare and Medicaid Programs:
Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers, 7610–7680
NOTICES
Inform Development of a National Youth Sports Strategy, 7391–7392
Meetings:
Health Information Technology Advisory Committee 2019 Schedule, 7392–7393
Renewal of Cooperative Agreement with the Institut Pasteur International Network, 7393–7394

Renewal of Cooperative Agreement with the Pan American Health Organization, 7393

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency
See U.S. Customs and Border Protection

Interior Department
See Fish and Wildlife Service

Internal Revenue Service
RULES
Utility Allowance Submetering, 7283–7285
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 7417–7419
Meetings:
Taxpayer Advocacy Panel Taxpayer Assistance Center Project Committee, 7419–7420
Taxpayer Advocacy Panel Taxpayer Communications Project Committee, 7419
Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee, 7418
Taxpayer Advocacy Panel's Toll-Free Phone Line Project Committee, 7420

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Carbon and Alloy Seamless Standard, Line and Pressure Pipe (Under 4.5 Inches) from Romania, 7345–7346
Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China, 7330–7337, 7339–7344
Polyvinyl Alcohol from the People's Republic of China, 7337–7339
Determination in Less Than Fair Value Investigation:
Certain Carbon and Alloy Steel Cut-to-Length Plate from Austria, 7344–7345
Determination of Sales at Less Than Fair Value:
Steel Racks and Parts Thereof from the People's Republic of China, 7326–7330

Labor Department
See Employment and Training Administration

Maritime Administration
NOTICES
Deepwater Port License Application:
SPOT Terminal Services, LLC, 7413–7415

National Archives and Records Administration
NOTICES
Change in Comment Process for Records Schedules, 7403–7404

National Institute of Standards and Technology
NOTICES
Meetings:
Information Security and Privacy Advisory Board, 7347–7348
Manufacturing Extension Partnership Advisory Board, 7346
Smart Grid Advisory Committee, 7346–7347

National Institutes of Health
NOTICES
Meetings:
Eunice Kennedy Shriver National Institute of Child Health and Human Development, 7395–7396
National Institute of Diabetes and Digestive and Kidney Diseases, 7394–7395
National Institute of Mental Health, 7395

National Oceanic and Atmospheric Administration
RULES
Atlantic Highly Migratory Species:
Atlantic Bluefin Tuna Fisheries, 7302–7303
Fisheries of the Exclusive Economic Zone off Alaska:
Pacific Cod by Catcher Vessels Greater than or Equal to 50 feet Length Overall using Hook-and-Line Gear in the Central Regulatory Area of the Gulf of Alaska, 7303
PROPOSED RULES
Fisheries off West Coast States:
Highly Migratory Fisheries; Amendment 6 to Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species; Authorization of Deep-set Buoy Gear, 7323–7325

National Science Foundation
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Grantee Reporting Requirements for Materials Research Science and Engineering Centers, 7405–7406
Presidential Awards for Excellence in Mathematics and Science Teaching, State Coordinator Survey, 7404–7405
Meetings:
Astronomy and Astrophysics Advisory Committee, 7404

Navy Department
NOTICES
Meetings:
Board of Advisers to The President of the Naval Postgraduate School Subcommittee, 7348

Occupational Safety and Health Review Commission
NOTICES
Privacy Act; Systems of Records, 7406–7410

Securities and Exchange Commission
NOTICES
Orders:
Nasdaq BX, Inc.; Nasdaq PHLX LLC, 7410–7411

Small Business Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 7411

State Department
NOTICES
Bureau of Political-Military Affairs; Rescission of Statutory Debarment of Rocky Mountain Instrument Company under the International Traffic in Arms Regulations, 7411–7412

Substance Abuse and Mental Health Services Administration

NOTICES
Meetings:
Center for Substance Abuse Treatment, 7396

Transportation Department
See Federal Aviation Administration
See Maritime Administration

Treasury Department
See Comptroller of the Currency
See Internal Revenue Service

U.S. Customs and Border Protection
NOTICES
Commercial Gaugers and Laboratories; Accreditation and Approval:
SGS North America, Inc. (East Alton, IL), 7396–7397

Veterans Affairs Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Notice of Lapse, Notice of Past Due Payment, 7420–7421
Meetings:
Advisory Committee on Homeless Veterans, 7420
Veterans' Family, Caregiver, and Survivor Advisory Committee; Amended, 7421

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 7610–7680
Health and Human Services Department, 7610–7680

Part III
Environmental Protection Agency, 7682–7712

Part IV
Health and Human Services Department, 7714–7791

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

7 CFR

Proposed Rules:

301 7304

14 CFR

39 (5 documents) ...7261, 7264, 7266, 7269, 7272

71 7274

Proposed Rules:

71 (2 documents) 7306, 7308

18 CFR

45 7274

46 7274

Proposed Rules:

33 7309

26 CFR

1 7283

33 CFR

100 7285

165 (4 documents) 7285, 7288, 7290, 7292

Proposed Rules:

100 7310

34 CFR

400 7294

401 7294

402 7294

403 7294

406 7294

410 7294

411 7294

413 7294

40 CFR

52 7299

63 7682

Proposed Rules:

52 7313

42 CFR

59 7714

Proposed Rules:

406 7610

407 7610

422 7610

423 7610

431 7610

438 7610

457 7610

482 7610

485 7610

45 CFR

Proposed Rules:

156 7610

170 7424

171 7424

47 CFR

Proposed Rules:

64 7315

50 CFR

635 7302

679 7303

Proposed Rules:

300 7323

Rules and Regulations

Federal Register

Vol. 84, No. 42

Monday, March 4, 2019

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0956; Product Identifier 2018–NM–041–AD; Amendment 39–19568; AD 2019–03–16]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Fokker Services B.V. Model F.27 Mark 100, 200, 300, 400, 500, 600, and 700 airplanes. This AD was prompted by a report of a main landing gear (MLG) collapse due to a broken drag stay; an investigation revealed that the drag stay failure was due to fatigue cracks, introduced by incorrect machining of the affected drag stay tube during production. This AD requires an inspection of the drag stay unit to determine the signal indication, and related investigative and corrective actions if necessary. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 8, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 8, 2019.

ADDRESSES: For Fokker service information identified in this final rule, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email *technicalservices@fokker.com;* internet *http://www.myfokkerfleet.com.* For Dowty Aerospace Landing Gear service information identified in this final rule, contact Safran Landing Systems, One Carbon Way, Walton, KY 41094; telephone (859) 525–8583; fax (859) 485–8827. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0956.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0956; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Fokker Services B.V. Model F.27 Mark 100, 200, 300, 400, 500, 600, and 700 airplanes. The NPRM published in the **Federal Register** on November 8, 2018 (83 FR 55825). The NPRM was prompted by a report of an MLG collapse due to a broken drag stay; an investigation revealed that the drag stay failure was due to fatigue cracks, introduced by incorrect machining of the affected drag stay tube during production. The NPRM proposed to require an inspection of the drag stay unit to determine the signal indication, and related investigative and corrective actions if necessary.

We are issuing this AD to address fatigue cracking, which could lead to MLG collapse and result in damage to the airplane during landing and consequent injury to passengers.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0015, dated January 25, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Fokker Services B.V. Model F.27 Mark 100, 200, 300, 400, 500, 600, and 700 airplanes. The MCAI states:

> In 1993, an occurrence was reported concerning an MLG collapse due to a broken drag stay on a Fokker F27 Mark 500 RFV (rough field version/configuration). The investigation revealed that the drag stay failure was due to fatigue cracks, introduced by incorrect machining (not smooth, with a notch) of the affected drag stay tube bore during production.
>
> This condition, if not detected and corrected, could lead to MLG collapse, possibly resulting in damage to the aeroplane during landing and consequent injury to occupants.
>
> To address this unsafe condition, DALG [Dowty Aerospace Landing Gear] issued SB [service bulletin] 32–169B and SB 32–82W (both later revised), and Fokker Services issued SB F27/32–167, to provide inspection instructions. Consequently, the Civil Aviation Authority of the Netherlands (CAA–NL) issued AD (BLA) 93–169 (later revised) [which corresponded to FAA AD 97–04–08, Amendment 39–9932 (62 FR 7924, February 21, 1997), and applies to certain Fokker Model F27 Mark 050, 100, 200, 300, 400, 600, and 700 airplanes], requiring a one-time ultrasonic inspection to identify the type of drag stay tube installed (with stepped or straight bore) on each affected drag stay unit, inspection of the affected drag stay tubes for the presence of cracks, and, depending on findings, re-identification.
>
> After CAA–NL AD (BLA) 93–169/2 was issued, another occurrence was reported on an F27 Mark 500 RFV. Investigation results determined that the drag stay tube of the second occurrence had not been inspected as required by CAA–NL AD (BLA) 93–169, due to misinterpretation of the instructions of Fokker SB F27/32–167. Prompted by these findings, Fokker Services issued SB F27–32–171, providing additional inspection instructions, and CAA–NL issued AD NL–2005–003 (EASA approval 2005–3869) [which corresponds to FAA AD 2006–25–06, Amendment 39–14847 (71 FR 71475, December 11, 2006) and applies to Fokker Services B.V. Model F.27 Mark 500 airplanes] to require repetitive inspections of the affected drag stay tubes to detect cracks and,

depending on findings, rework or replacement.

Since those SBs and [CAA–NL] ADs were issued, the applicable CMM [component maintenance manual] were changed, although with incorrect P/N information, as a result of which an affected drag stay tube with a non-conforming bore radius may inadvertently have been installed on an aeroplane. Prompted by these findings, the applicable CMM were corrected and re-issued, and SLS issued Service Letter (SL) F27–W–8 to inform the operators, and Fokker Services introduced the relevant corrections in the F27 Mark 100 through Mark 700 Illustrated Parts Catalogue (IPC) in September 2017.

Installation of an affected drag stay tube with a non-conforming bore radius, on an MLG drag stay unit that has been re-identified, *i.e.* not subject to the repetitive inspections as required by CAA–NL AD NL–2005–003, would reintroduce the unsafe condition as originally addressed by the SBs and ADs referred to above. To address this potential unsafe condition, Fokker Services issued SBF27–32–173 to provide instructions to inspect, remove/discard or re-identify the affected drag stay tubes.

For the reasons described above, this [EASA] AD requires a one-time inspection of the affected drag stay units to determine whether an affected drag stay tube is installed, repetitive inspections of those that have an affected drag stay tube installed, and, depending on findings, accomplishment of applicable corrective action(s) [which includes replacement of the drag stay tube].

With the issuance of this [EASA] AD and [EASA] AD 2018–0016 [dated January 25, 2018], the requirements of CAA–NL AD (BLA) 93–169/2 dated 29 April 1994 are no longer necessary and that AD is also cancelled.

EASA AD 2018–0016, dated January 25, 2018, applies to Model F.27 Mark 500 airplanes and has been added to the Required Airworthiness Action List.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0956.

Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Fokker Services B.V. has issued Service Bulletin SBF27–32–173, dated November 30, 2017. This service information describes procedures for an inspection of the drag stay unit to determine the signal indication, and related investigative and corrective actions if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

Dowty Aerospace Landing Gear issued Service Bulletin 32–82W, Revision 2, dated July 29, 1994; and Service Bulletin 32–169B, Revision 2, dated July 29, 1994. This service information describes procedures for reworking the drag stay tube. These documents are distinct since they apply to different airplane models.

This service information can be obtained from SAFRAN Landing Systems by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 1 airplane of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × $85 per hour = $170	$0	$170	$170

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2019–03–16 Fokker Services B.V. Airplanes: Docket No. FAA–2018–0956; Product Identifier 2018–NM–041–AD.

(a) Effective Date

This AD is effective April 8, 2019.

(b) Affected ADs

This AD affects AD 2006–25–06, Amendment 39–14847 (71 FR 71475, December 11, 2006) (''AD 2006–25–06'') and AD 97–04–08, Amendment 39–9932 (62 FR 7924, February 21, 1997) (''AD 97–04–08'').

(c) Applicability

This AD applies to all Fokker Services B.V. Model F.27 Mark 100, 200, 300, 400, 500, 600, and 700 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 32, Main landing gear.

(e) Reason

This AD was prompted by a report of a main landing gear (MLG) collapse due to a broken drag stay; an investigation revealed that the drag stay failure was due to fatigue cracks, introduced by incorrect machining of the affected drag stay tube during production. We are issuing this AD to address fatigue cracking, which could lead to MLG collapse and result in damage to the airplane during landing and consequent injury to passengers.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Definitions

(1) For purposes of this AD, an affected drag stay unit is SAFRAN Landing Systems (previously Messier-Dowty, Dowty Aerospace) MLG drag stay unit, part number (P/N) 200261001, P/N 200261002, P/N 200261003, P/N 200261004, P/N 200485001, P/N 200485002, P/N 200485003, P/N 200485004, P/N 200684001, P/N 200684002, P/N 200684003, or P/N 200684004.

(2) For purposes of this AD, an affected drag stay tube is a SAFRAN Landing Systems (previously Messier-Dowty, Dowty Aerospace) MLG drag stay tube, P/N 200259300, which has a change in section (stepped bore).

(h) Configuration Verification of the Drag Stay Units

Within 12 months after the effective date of this AD, do an ultrasonic inspection of each affected drag stay unit to determine the configuration of the drag stay tube, in accordance with step F. of the Accomplishment Instructions of Fokker Service Bulletin SBF27–32–173, dated November 30, 2017.

(i) Re-Identification of an Affected Drag Stay Unit

(1) If, during the inspection required by paragraph (h) of this AD, an affected drag stay unit is found to have a straight bore drag stay tube, P/N 200485300, installed: Before further flight, re-identify that affected drag stay unit in accordance with step I.(2), I.(3), or I.(4), as applicable, of the Accomplishment Instructions of Fokker Service Bulletin SBF27–32–173, dated November 30, 2017.

(2) If, during the inspection required by paragraph (h) of this AD, an affected drag stay unit is found to have an affected drag stay tube, P/N 200259300, installed with a correct radius: Before further flight, re-identify the affected drag stay unit in accordance with step J.(1), J.(2), or J.(3), as applicable, of the Accomplishment Instructions of Fokker Service Bulletin SBF27–32–173, dated November 30, 2017.

(3) If, during the inspection required by paragraph (h) of this AD, an affected drag stay unit is found to have an affected drag stay tube, P/N 200259300, installed with an incorrect radius: Before further flight, re-identify the affected drag stay unit in accordance with step K.(1), K.(2), or K.(3), as applicable, of the Accomplishment Instructions of Fokker Service Bulletin SBF27–32–173, dated November 30, 2017.

(j) Inspection and Corrective Action for Certain Drag Stay Unit Part Numbers

For affected drag stay units having P/N 200261002, P/N 200261003, P/N 200485002, P/N 200485003, P/N 200684002, or P/N 200684003: Within 12 months after the effective date of this AD, do an ultrasonic inspection of the affected drag stay tube for any cracking, in accordance with step G. of the Accomplishment Instructions of Fokker Service Bulletin SBF27–32–173, dated November 30, 2017.

(1) If, during the ultrasonic inspection, a crack indication is found, before further flight, replace the affected drag stay tube with a serviceable part, in accordance with step H. of the Accomplishment Instructions of Fokker Service Bulletin SBF27–32–173, dated November 30, 2017.

(2) For affected drag stay units having P/N 200261002, P/N 200485002, or P/N 200684002 (drag stay units with incorrect bore radius drag stay tubes): If, during the ultrasonic inspection, no indication of cracking is found, within 1,500 flight cycles after that inspection, and, thereafter, at intervals not to exceed 1,500 flight cycles until the next scheduled MLG overhaul, repeat the ultrasonic inspection of the affected drag stay tube in accordance with step G. of the Accomplishment Instructions of Fokker Service Bulletin SBF27–32–173, dated November 30, 2017.

(k) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, a drag stay unit (which includes installation of a replacement MLG), unless it has been determined that no affected drag stay tube is installed; or the installed affected drag stay tube has been reworked during the MLG overhaul in accordance with the instructions of Appendix B of Dowty Aerospace Landing Gear Service Bulletin 32–82W, Revision 2, dated July 29, 1994 (for Model F.27 Mark 500 airplanes), or Dowty Aerospace Landing Gear Service Bulletin 32–169B, Revision 2, dated July 29, 1994 (for Model F.27 Mark 100, 200, 300, 400, 600, and 700 airplanes), as applicable; or has passed an inspection (confirmed correct bore radius) in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF27–32–173, dated November 30, 2017. For the purpose of this AD, removal of an MLG or an affected drag stay unit from an airplane and re-installing that MLG or drag stay unit on the same airplane is not ''installation.''

(l) Terminating Action for Other ADs

Accomplishing the actions required by this AD terminates all requirements of AD 2006–25–06 and AD 97–04–08.

(m) Credit for Previous Actions

This paragraph provides credit for the applicable actions specified in paragraph (k) of this AD, if those actions were performed before the effective date of this AD using Dowty Aerospace Landing Gear Service Bulletin 32–82W, Revision 1, dated September 10, 1993, or Dowty Aerospace Landing Gear Service Bulletin 32–169B, Revision 1, dated September 10, 1993.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (o)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved

by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Fokker Services B.V.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0015, dated January 25, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0956.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(3) Dowty Aerospace Landing Gear service information identified in this AD, and not incorporated by reference, is available from Safran Landing Systems, One Carbon Way, Walton, KY 41094; telephone (859) 525–8583; fax (859) 485–8827.

(p) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Fokker Service Bulletin SBF27–32–173, dated November 30, 2017.

(ii) [Reserved]

(3) For Fokker service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email *technicalservices@fokker.com;* internet *http://www.myfokkerfleet.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 14, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–03267 Filed 3–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0959; Product Identifier 2018–NM–123–AD; Amendment 39–19576; AD 2019–03–24]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–400 series airplanes. This AD was prompted by reports of cracking in the splice plate on the lower sill of the overwing emergency exit doors. This AD requires repetitive inspections for such cracking and applicable on-condition actions. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 8, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 8, 2019.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0959.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0959; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: James Guo, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5357; fax: 562–627–5210; email: *james.guo@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 737–400 series airplanes. The NPRM published in the **Federal Register** on November 8, 2018 (83 FR 55828). The NPRM was prompted by reports of cracking in the splice plate on the lower sill of the overwing emergency exit doors. The NPRM proposed to require repetitive inspections for such cracking and applicable on-condition actions. We are issuing this AD to address cracking in the splice plate, which, if not addressed, could result in the inability of a principal structural element to sustain limit loads and possible rapid decompression of the fuselage.

Comments

We gave the public the opportunity to participate in developing this final rule. We have considered the comments received. Boeing indicated no objection to the NPRM. Commenters Zack Jones and Josep Clapes stated their support for the NPRM.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Requirements Bulletin 737–53A1380 RB, dated July 18, 2018. This service information describes procedures for repetitive high frequency eddy current inspections for cracking in the splice plate on the lower sill of the overwing emergency exit doors and applicable on-condition actions. This service information is reasonably available

because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 85 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive inspections ...	2 work-hours × $85 per hour = $170 per inspection cycle.	$0	$170 per inspection cycle.	$14,450 per inspection cycle.

We estimate the following costs to do any necessary on-condition actions that would be required. We have no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 18 work-hours × $85 per hour = $1,530	Up to $7,646	Up to $9,176.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2019–03–24 The Boeing Company: Amendment 39–19576; Docket No. FAA–2018–0959; Product Identifier 2018–NM–123–AD.

(a) Effective Date

This AD is effective April 8, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 737–400 series airplanes, certificated in any category, line numbers 1487 through 3132 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of cracking in the splice plate on the lower sill of the overwing emergency exit doors. We are issuing this AD to address cracking in the splice plate, which, if not addressed, could result in the inability of a principal structural element to sustain limit loads and possible rapid decompression of the fuselage.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 737–53A1380 RB, dated July 18, 2018, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 737–53A1380 RB, dated July 18, 2018.

Note 1 to paragraph (g) of this AD: Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 737–53A1380, dated July 18, 2018, which is referred to in Boeing Alert Requirements Bulletin 737–53A1380 RB, dated July 18, 2018.

(h) Exceptions to Service Information Specifications

(1) For purposes of determining compliance with the requirements of this AD: Where Boeing Alert Requirements Bulletin 737–53A1380 RB, dated July 18, 2018, uses the phrase ''the original issue date of Requirements Bulletin 737–53A1380 RB,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Requirements Bulletin 737–53A1380 RB, dated July 18, 2018, specifies contacting Boeing for repair instructions: This AD requires doing the repair and applicable on-condition actions before further flight using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact James Guo, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5357; fax: 562–627–5210; email: *james.guo@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (k)(3) and (k)(4) of this AD.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Requirements Bulletin 737–53A1380 RB, dated July 18, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 19, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–03407 Filed 3–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–9189; Product Identifier 2016–NM–114–AD; Amendment 39–19578; AD 2019–03–26]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 737–600, –700, –700C, -800, -900, and –900ER series airplanes. This AD was prompted by reports of passenger service units (PSUs) becoming detached from the supporting airplane structure in several Model 737 series airplanes. This AD requires modifying the PSUs and life vest panels by replacing the existing inboard lanyard and installing two new lanyards on the outboard edge of the PSUs and life vest panels; measuring the distance between the hooks of the torsion spring of the lanyard assembly; replacing discrepant lanyard assemblies; and re-identifying serviceable lanyard assemblies. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 8, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 8, 2019.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9189.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–9189; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Scott Craig, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3566; email: *michael.s.craig@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 737–600, –700, –700C, –800, -900, and –900ER series airplanes. The NPRM published in the **Federal Register** on October 13, 2016 (81 FR 70647). The NPRM was prompted by reports of PSUs becoming detached from the supporting airplane structure in several Model 737 series airplanes during survivable accidents. The NPRM proposed to require modifying the PSUs and life vest panels by removing the existing inboard lanyard and installing two new lanyards on the outboard edge of the PSUs and life vest panels.

We issued a supplemental NPRM (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain The Boeing Company Model 737–600, –700, –700C, -800, -900, and –900ER series airplanes. The SNPRM published in the **Federal Register** on September 14, 2018 (83 FR 46666). We issued the SNPRM to add airplanes to the applicability, add a measurement of the distance between the hooks of the torsion spring of the lanyard assembly, replace discrepant lanyard assemblies, and re-identify serviceable lanyard assemblies.

We are issuing this AD to address PSUs and life vest panels detaching from the supporting airplane structure, which could lead to passenger injuries and impede passenger and crew egress during evacuation.

Comments

We gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the SNPRM and the FAA's response to each comment.

Request To Include PSU-Mounted Liquid Crystal Display (LCD) Panels

JeJu Air requested that we consider adding actions similar to those in the SNPRM for PSU-mounted LCD panels. JeJu Air noted that they experienced an incident in which four PSU-mounted LCD panels dropped during flight, resulting in minor injuries to several passengers. JeJu Air stated that PSU-mounted LCD panels are not subject to routine inspections through a manufacturer's maintenance planning document. The commenter added that the PSU-mounted LCD panels are heavier than normal PSUs and therefore could be riskier for passengers if they fall.

We acknowledge the commenter's concern. However, making the requested change would require issuance of a second SNPRM with another public comment period, delaying the issuance of a final rule. To delay this action would be inappropriate, since we have determined that an unsafe condition exists and that PSU modifications and lanyard replacements must be made to ensure continued safety. We will consider additional rulemaking to address PSU-mounted LCD panels. We have not changed this AD in this regard.

Request To Revise the Applicability

Boeing requested that we revise the applicability of the proposed AD (in the SNPRM) to The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes ''as identified in Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018.'' Boeing stated that including airplanes beyond those identified in Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018, would not add to the safety of the operating fleet. Boeing added that airplanes with potentially affected lanyard assemblies, whether included in reworked airplanes, installed during production, or issued in kits, are all categorized and addressed in Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018.

We disagree with the commenter's request. The PSUs and lanyard assemblies are rotable parts that can be installed on airplanes that previously did not have affected PSUs and lanyard assemblies installed. Therefore, the applicability of this AD, ''all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category, without a Boeing Sky Interior (BSI),'' ensures that no PSUs without the updated lanyard assemblies are installed and the unsafe condition is addressed on all affected airplanes. We have not changed this AD in this regard.

Request To Correct a Service Bulletin Effectivity Range

Boeing requested that we revise the ''Differences Between This SNPRM and the Service Information'' section of the SNPRM to note that the effectivity of Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018, is limited to ''line numbers 1 through 6099,'' rather than ''line numbers 1 through 6009.''

We acknowledge this typographical error. However, the ''Differences Between This SNPRM and the Service Information'' section does not carry over into this AD. Therefore, we have not changed this AD in this regard.

Request To Remove a Requirement To Add an Identifying Mark

American Airlines (AAL) requested that we remove a requirement in the proposed AD (in the SNPRM) to identify new lanyard assemblies as serviceable by adding a permanent white mark. AAL noted that Figure 1, step 3 of Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018, which is Required for Compliance (RC), says to ''Identify the lanyard assembly as serviceable with a permanent white mark, that can be easily seen when the PSU is lowered.'' The commenter stated that new lanyards received in certain kits are deemed serviceable, but not identified with a white mark. AAL asked why the parts would be marked at installation rather than inspection or fabrication, which seems to place the burden on installers to determine the lanyard assembly is serviceable.

We disagree with the commenter's request. Some previously delivered lanyard assembly kits contained lanyards that were manufactured incorrectly and might not properly secure the PSU in the event of an accident. By inspecting and identifying the lanyard assembly during installation, operators can ensure that the correct lanyard assembly is installed on an airplane. On some airplanes, a correct lanyard assembly may already be installed and only needs to be identified with a white mark. Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018, clearly identifies a serviceable lanyard assembly, and the white mark is an important part of that definition. We have not changed this AD in this regard.

Request To Provide More Details on PSU Removal and Installation

AAL requested that the Boeing 737NG Aircraft Maintenance Manual (AMM) 25–23–61 provide more detailed instructions for removing and installing the PSU. AAL noted that Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018, provides detailed instructions for attaching the lanyard clip to the PSU rail, but the AMM does not provide the same level of instructions. We infer that the commenter is asking us to require Boeing to update the AMM to provide more details.

We acknowledge the commenter's request. The AMM is identified as an affected publication in Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018; however, this AD does not require compliance with the AMM, and the AMM is not part of an RC step in the service bulletin. The AMM is referred to as one source of information for removing and installing the PSU, but as noted in paragraph (i)(4)(ii) of this AD, operators may rely on their own accepted methods in accordance with the operator's maintenance or inspection program for those steps. In addition, Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018, provides adequate details to address the unsafe condition in this AD. Therefore, we have not changed this AD in this regard.

Request To Revise the Costs of Compliance

AAL stated that Boeing Service Bulletin 737–25–1707, dated September 24, 2015, provided a work-hours task total of 1.35 work-hours per PSU. The commenter added that Boeing Service

Bulletin 737–25–1707, Revision 1, dated May 18, 2018, increased the scope of work done on the PSU, but reduced the work-hours task total to 0.4 work-hours per PSU. We infer that the commenter is suggesting that the work-hour estimates should be revised in the final rule.

We agree to clarify the Costs of Compliance section of this AD. Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018, separates the work-hour estimates into multiple tables based on group configurations and the type of work to be done. Adding all of the work-hours from the applicable tables for a given configuration, the total work-hours estimate is higher for certain configurations. Therefore, the estimated costs in this AD represent the highest work-hours and parts cost for all configurations. We have not changed this AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the SNPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the SNPRM.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018. This service information describes procedures for modifying the PSUs and life vest panels by replacing the existing inboard lanyard and installing two new lanyards on the outboard edge of the PSUs and life vest panels, measuring the distance between the hooks of the torsion spring of the lanyard assembly, replacing any discrepant lanyard assemblies, and re-identifying serviceable lanyard assemblies. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 2,015 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Measurement and modification.	Up to 75 work-hours × $85 per hour = Up to $6,375.	Up to $11,760	Up to $18,135	Up to $36,542,025.

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all known costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2019–03–26 The Boeing Company: Amendment 39–19578; Docket No. FAA–2016–9189; Product Identifier 2016–NM–114–AD.

(a) Effective Date

This AD is effective April 8, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes, certificated in any category, without a Boeing Sky Interior (BSI).

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by reports of passenger service units (PSUs) becoming detached from the supporting airplane structure in several Model 737 series airplanes during survivable accidents. We are issuing this AD to address PSUs and life vest panels detaching from the supporting airplane structure, which could lead to passenger injuries and impede passenger and crew egress during evacuation.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Within 60 months after the effective date of this AD, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018.

(h) Parts Installation Prohibition

As of the applicable time specified in paragraph (h)(1) or (h)(2) of this AD, no person may install on any airplane a PSU or life vest panel, unless the lanyard assembly has been updated as required by paragraph (g) of this AD.

(1) For airplanes that have PSUs or life vest panels without the updated lanyard assemblies installed: After modification of the airplane as required by this AD.

(2) For airplanes that have PSUs or life vest panels with the updated lanyard assemblies installed: As of the effective date of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (i)(4)(i) and (i)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

For more information about this AD, contact Scott Craig, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3566; email: *michael.s.craig@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Service Bulletin 737–25–1707, Revision 1, dated May 18, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 14, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–03408 Filed 3–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0963; Product Identifier 2018–NM–135–AD; Amendment 39–19566; AD 2019–03–14]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Dassault Aviation Model FAN JET FALCON and FAN JET FALCON SERIES C, D, E, F, and G airplanes. This AD was prompted by a determination that new and more restrictive airworthiness limitations and maintenance requirements are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations and maintenance requirements. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 8, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 8, 2019.

ADDRESSES: For service information identified in this final rule, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *http://www.dassaultfalcon.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0963.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0963; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any

comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Dassault Aviation Model FAN JET FALCON and FAN JET FALCON SERIES C, D, E, F, and G airplanes. The NPRM published in the **Federal Register** on November 23, 2018 (83 FR 59326). The NPRM was prompted by a determination that new and more restrictive airworthiness limitations and maintenance requirements are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations and maintenance requirements. We are issuing this AD to address, among other things, fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0193, dated September 3, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Dassault Aviation Model FAN JET FALCON and FAN JET FALCON SERIES C, D, E, F, and G airplanes. The MCAI states:

> In June 1988, the Federal Aviation Administration sponsored a conference on ageing aircraft, during which the decision was taken to pay particular attention to those. The ATA [Air Transport Association] and the AIA [Aerospace Industries Association] committed themselves to identify and to set up procedures to ensure continued structural integrity on ageing aircraft. Prompted by these actions, Dassault developed the SSIP [Supplemental Structural Inspection Program], aiming to guarantee the airworthiness of the Fan Jet Falcon aeroplane which reach and exceed half of the Limit of Validity. The airworthiness limitations and certification maintenance instructions for the affected Fan Jet Falcon aeroplanes, which are approved by EASA, are currently defined and published in the ALS [airworthiness limitations section]. These instructions have been identified as mandatory for continued airworthiness.
>
> Failure to accomplish these instructions could result in an unsafe condition.
>
> Previously, EASA issued AD 2008–0221 to require accomplishment of the maintenance tasks, and implementation of the airworthiness limitations, as specified in ALS at Revision 7.
>
> Since that [EASA] AD was issued, Dassault issued ALS Revisions 8 and 9, which introduced new and more restrictive maintenance requirements and/or airworthiness limitations.
>
> For the reason described above, this [EASA] AD takes over the requirements for Fan Jet Falcon aeroplanes from EASA AD 2008–0221 and requires accomplishment of the actions specified in the ALS.
>
> Once new [EASA] ADs have been published for all the types addressed by EASA AD 2008–0221, EASA plans to cancel that AD.

The unsafe condition is fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane. Because we determined that a separate FAA AD should be issued for each airplane model due to different ALS requirements, we did not issue an AD that corresponded to EASA AD 2008–0221.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0963.

Comments

We gave the public the opportunity to participate in developing this final rule. We have considered the comment received; the commenter, Bienvenu Badinenganyi, stated no objection to the NPRM.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Dassault has issued Chapter 5–40–01, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual. This service information includes life limits for certain airframe components, and describes airworthiness limitations for safe life limits and certification maintenance requirements. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 61 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

We have determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although we recognize that this number may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet, we have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs

applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2019–03–14 Dassault Aviation: Amendment 39–19566; Docket No. FAA–2018–0963; Product Identifier 2018–NM–135–AD.

(a) Effective Date

This AD is effective April 8, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Dassault Aviation Model FAN JET FALCON and FAN JET FALCON SERIES C, D, E, F, and G airplanes, certificated in any category, all serial numbers, on which the Dassault Fan Jet Falcon Supplemental Structural Inspection Program (Dassault Service Bulletin (SB) 730), has been embodied into the airplane's maintenance program.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a determination that new and more restrictive airworthiness limitations and maintenance requirements are necessary. We are issuing this AD to address, among other things, fatigue cracking and damage in principal structural elements; such fatigue cracking and damage could result in reduced structural integrity of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the airworthiness limitations specified in Chapter 5–40–01, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual. The initial compliance time for accomplishing the actions is at the applicable time specified in Chapter 5–40–01, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual; or within 90 days after the effective date of this AD; whichever occurs later. Where the threshold column in the table in paragraph B, Mandatory Maintenance Operations, of Chapter 5–40–01, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual specifies a compliance time in years, those compliance times start from the date of issuance of the original airworthiness certificate or date of issuance of the original export certificate of airworthiness.

(h) No Alternative Actions or Intervals

After accomplishing the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or European Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0193, dated September 3, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0963.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Chapter 5–40–01, Airworthiness Limitations, DMD 44729, Revision 9, dated November 29, 2017, of the Dassault Aviation Falcon 20 Maintenance Manual.

(ii) [Reserved]

(3) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *http://www.dassaultfalcon.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on February 21, 2019.

Dionne Palermo,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–03411 Filed 3–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–1006; Product Identifier 2018–NM–142–AD; Amendment 39–19565; AD 2019–03–13]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.) Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Gulfstream Aerospace LP Model Gulfstream G150 airplanes. This AD was prompted by reports of corrosion in the solder joints of the upper and lower front relay box connectors to the printed circuit board. This AD requires replacement of the existing relay boxes with modified boxes. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 8, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of April 8, 2019.

ADDRESSES: For service information identified in this final rule, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D–25, Savannah, GA 31402–2206; telephone 800–810–4853; fax 912–965–3520; email *pubs@gulfstream.com;* internet *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1006.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1006; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Gulfstream Aerospace LP Model Gulfstream G150 airplanes. The NPRM published in the **Federal Register** on December 11, 2018 (83 FR 63596). The NPRM was prompted by reports of corrosion in the solder joints of the upper and lower front relay box connectors to the printed circuit board. The NPRM proposed to require replacement of the existing relay boxes with modified boxes.

We are issuing this AD to address corrosion in the front relay box connector solder joints. If not addressed, this condition could cause false crew alerting system (CAS) messages, such as slats unbalance, auto slats fail, and Mach trim fail, which could interfere with continued safe operation of the airplane.

The Civil Aviation Authority of Israel (CAAI), which is the aviation authority for Israel, has issued Israeli Airworthiness Directive ISR–I–24–2018–09–7, dated October 1, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Gulfstream Aerospace LP Model Gulfstream G150 airplanes. The MCAI states:

> The existing Upper and Lower Front Relay Box might be prone to corrosion in the relay box connector's solder joint to the printed circuit board. As a result various CAS [crew alerting system] messages such as slats unbalance and auto slats fail, Mach trim fail, etc . . . might be reported [and could interfere with continued safe operation of the airplane]. To prevent this condition, replacement of existing relay boxes with modified boxes featuring an added acrylic conformal coating should be performed.
>
> Five occurrences on G150 model in last 3 years had been reported.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1006.

Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Gulfstream has issued Service Bulletin 150–24–193, dated March 30, 2018. This service information describes procedures for removing and replacing the upper and lower front relay boxes. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 81 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
220 work-hours × $85 per hour = $18,700	$20,083	$38,783	$3,141,423

According to the manufacturer, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all known costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2019–03–13 Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft Industries, Ltd.): Amendment 39–19565; Docket No. FAA–2018–1006; Product Identifier 2018–NM–142–AD.

(a) Effective Date

This AD is effective April 8, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace LP (Type Certificate previously held by Israel Aircraft Industries, Ltd.) Model Gulfstream G150 airplanes, certificated in any category, serial numbers 201 through 326 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical power.

(e) Reason

This AD was prompted by reports of corrosion in the solder joints of the upper and lower front relay box connectors to the printed circuit board. We are issuing this AD to address corrosion in the front relay box connector solder joints. If not addressed, this condition could cause false crew alerting system (CAS) messages, such as slats unbalance, auto slats fail, and Mach trim fail, which could interfere with continued safe operation of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Replacement

Within 36 months after the effective date of this AD, remove the upper front relay box, Israel Aerospace Industries (IAI) part number (P/N) 25G8130301–510/–512/–514/–516, and replace with IAI P/N 25G8130301–516, upgraded to MOD A, and remove the lower front relay box, IAI P/N 25G8130300–512/–516/–518/–520, and replace with an improved lower front relay box, IAI P/N 25G8130300–520, upgraded to MOD A, in accordance with the Accomplishment Instructions of Gulfstream Service Bulletin 150–24–193, dated March 30, 2018.

(h) Parts Installation Prohibition

As of the applicable compliance time specified in paragraph (h)(1) or (h)(2) of this AD, do not install relay box IAI P/N 25G8130301–510/–512/–514/–516 or IAI P/N 25G8130300–512/–516/–518/–520 on any airplane, except relay box IAI P/N 25G8130301–516 or IAI P/N 25G8130300–520 that has been upgraded to MOD A as specified in paragraph (g) of this AD may be installed.

(1) For airplanes that have IAI P/N 25G8130301–510/–512/–514/–516 or IAI P/N 25G8130300–512/–516/–518/–520 installed as of the effective date of this AD: After modification of the airplane as required by this AD.

(2) For airplanes that do not have IAI P/N 25G8130301–510/–512/–514/–516 or IAI P/N 25G8130300–512/–516/–518/–520 installed as of the effective date of this AD: As of the effective date of this AD.

(i) No Parts Return or Reporting Requirement

(1) Although Gulfstream Service Bulletin 150–24–193, dated March 30, 2018, specifies to return parts to the manufacturer, this AD does not include that requirement.

(2) Although Gulfstream Service Bulletin 150–24–193, dated March 30, 2018, specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the Civil Aviation Authority of Israel (CAAI); or the CAAI's authorized Designee. If approved

by the CAAI Designee, the approval must include the Designee's authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Israeli Airworthiness Directive ISR–I–24–2018–09–7, dated October 1, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–1006.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Gulfstream Service Bulletin 150–24–193, dated March 30, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D–25, Savannah, GA 31402–2206; telephone 800–810–4853; fax 912–965–3520; email *pubs@gulfstream.com;* internet *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm*.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Des Moines, Washington, on February 14, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–03406 Filed 3–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0256; Airspace Docket No. 18–AEA–11]

RIN 2120–AA66

Amendment of Class D Airspace and Class E Airspace; Schenectady, NY, Ithaca, NY, and Albany, NY

Correction

In rule document 2019–02687, appearing on pages 4991 through 4993, in the issue of Wednesday, February 20, 2019, make the following correction:

§ 71.1 [Corrected]

■ On page 4992, in the second column, under the heading ''AEA NY E2 Ithaca, NY [Amended]'', in the third line, the entry that reads ''(Lat. 42°29′29″ N, long. 76°27′3″ W)'' should read ''(Lat. 42°29′29″ N, long. 76°27′31″ W)''.

[FR Doc. C1–2019–02687 Filed 3–1–19; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 45 and 46

[Docket No. RM18–15–000; Order No. 856]

Interlocking Officers and Directors; Requirements for Applicants and Holders

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: In this final rule, the Federal Energy Regulatory Commission (Commission) amends its regulations related to interlocking officers and directors to clarify and update the requirements for both applicants and holders.

DATES: This rule will become effective May 3, 2019.

FOR FURTHER INFORMATION CONTACT:

Lindsay Orphanides (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8372, *lindsay.orphanides@ferc.gov*.

Mary Ellen Stefanou (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8989, *mary.stefanou@ferc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

1. On July 19, 2018, the Commission issued a Notice of Proposed Rulemaking (NOPR),[1] proposing to revise parts 45 and 46 of the Commission's regulations related to interlocking officers and directors to clarify and update the requirements for both applicants and holders. The Commission proposed to: (1) Update its regulations to reflect statutory changes to the circumstances in which an applicant who would otherwise require Commission authorization to hold an interlocking position need not do so; (2) revise its regulations to clarify its position on late-filed applications and informational reports; (3) revise its regulations to clarify that an interlock holder is not required to file a notice of change when merely changing positions within a holding company; (4) revise its regulations to state that applicants do not need to list in their applications public utilities that do not have officers or directors; (5) revise its regulations with regard to public utilities owned by a natural person; and (6) update its regulations to remove § 46.2(b), which contains definitions and phrases now rendered obsolete.

2. Comments were filed by Edison Electric Institute (EEI), NRG Power Marketing LLC (NRG), Just Energy (U.S.) Corp. (Just Energy), Electric Power Supply Association (EPSA), National Rural Electric Cooperative Association (NRECA), National Grid USA (National Grid), and Golden Spread Electric Cooperative, Inc. (Golden Spread). All comments were generally supportive of the proposed changes. Some commenters requested clarification on certain proposed changes, while others proposed additional changes. We address these issues below.

II. Discussion

A. No Need for Commission Approval of Interlocking Director and Officer Positions in Certain Circumstances

1. Proposal

3. Section 45.2 of the Commission's regulations describes the types of interlocking positions that require Commission authorization, including those between a public utility and entities authorized by law to underwrite or participate in the marketing of public utility securities.[2] However, in 1999, Congress amended Federal Power Act

[1] *Revisions to Parts 45 and 46 of the Commission's Regulations,* Notice of Proposed Rulemaking, 83 FR 37450 (Aug. 1, 2018), 164 FERC ¶ 61,032 (2018) (NOPR).

[2] 18 CFR 45.2(b)(2).

(FPA) section 305(b)(2) to provide that an applicant for certain interlocking positions is no longer required to obtain Commission authorization to hold such positions.[3] In the NOPR, the Commission proposed to revise § 45.2 of its regulations to add that an applicant for an interlocking position between a public utility and a ''bank, trust company, banking association, or firm that is authorized by law to underwrite or participate in the marketing of public utility securities,''[4] does not need Commission authorization when:

- The person does not participate in any deliberations or decisions of the public utility regarding the selection of the bank, trust company, banking association, or firm to underwrite or participate in the marketing of securities of the public utility, if the person serves as an officer or director of a bank, trust company, banking association, or firm that is under consideration in the deliberation process;
- the bank, trust company, banking association, or firm of which the person is an officer or director does not engage in the underwriting of, or participate in the marketing of, securities of the public utility of which the person holds the position of officer or director;
- the public utility for which he/she serves or proposes to serve as an officer or director selects underwriters by competitive procedures; or
- the issuance of securities of the public utility for which the person serves or proposes to serve as an officer or director has been approved by all Federal and State regulatory agencies having jurisdiction over the issuance.[5]

2. Comments

4. EEI, Golden Spread, Just Energy, and NRECA all support the Commission's proposed revision to § 45.2 of its regulations.

5. Golden Spread states in its comments that it is unclear from the NOPR if the Commission will require continued reporting of interlocking positions between a public utility and a bank, trust company, banking association, or firm that is authorized by law to underwrite or participate in the marketing of public utility securities in Form No. 561. If not, Golden Spread states that the Commission may wish to cross reference to § 45.2 or clarify § 46.5 of its regulations.[6]

3. Commission Determination

6. We will revise the language in § 45.2 as proposed in the NOPR, which brings the Commission's regulations into conformance with the changes made by Congress to FPA section 305(b)(2) in 1999.

7. In response to Golden Spread's comments, we clarify that the Commission will continue to require the reporting of interlocking positions between a public utility and a bank, trust company, banking association, or firm that is authorized by law to underwrite or participate in the marketing of public utility securities in Form No. 561 under § 46.5 of the Commission's regulations as the statutory directive to report such information has not changed.[7]

B. Flexibility To Consider Late-Filed Applications and Informational Reports

1. Proposal

8. The Commission proposed in the NOPR to revise § 45.3(a) of its regulations, which currently states that ''late-filed applications will be denied'' and § 45.9(b), which currently states that ''[f]ailure to timely file the informational report will constitute a failure to satisfy this condition and will constitute automatic denial.'' The Commission stated that it expects its regulations to be followed but recognizes that good faith errors and oversights may occasionally result in the inadvertent violation of the timing of FPA section 305(b)'s filing requirements. In addition, the Commission stated that it expects applicants to be attentive to their obligation to timely file for the required authorizations and make every effort to ensure they act in accordance with the statutory directives in FPA section 305(b). Further, the Commission stated that, if an error or oversight occurs, it expects that those errors and oversights will be expeditiously identified and rectified, and applications to hold interlocking director positions be promptly filed. Therefore, the Commission proposed to delete the above-quoted language, and replace it with language providing for consideration of late-filed applications for interlocking positions on a case-by-case basis.[8]

2. Comments

9. EEI, Golden Spread, Just Energy, National Grid, NRECA, and NRG all support the Commission's proposed changes to §§ 45.3(a) and 45.9(b). EEI takes issue with the Commission's statement in the NOPR preamble that, ''[i]n cases where occasional errors and oversights occur, the Commission expects that those errors and oversights will be expeditiously identified and rectified, and applications to hold interlocking director positions promptly filed.''[9] To avoid ''misinterpretation,'' EEI encourages the Commission to restate the quoted provision to say: ''When errors and oversights are discovered, the Commission expects that those errors and oversights will be expeditiously rectified, and if required applications will be promptly filed.''[10]

3. Commission Determination

10. We adopt the changes to §§ 45.3(a) and 45.9(b) of the Commission's regulations proposed in the NOPR that will allow for consideration of late-filed applications for interlocking positions on a case-by-case basis.[11] We do not think that it is in the public interest to deny otherwise-qualified applicants' late-filed applications and informational filings made under these regulations when the late filing is due solely to good faith errors and oversights, and the error or oversight is promptly identified and expeditiously rectified.

11. We decline to amend our statement in the NOPR preamble to state that the Commission's expectation is that errors and oversights be expeditiously rectified ''when errors and oversights are discovered,'' as suggested by EEI. We expect that errors and oversights be both promptly identified and expeditiously rectified, and we reiterate our expectation—grounded in the statute[12]—that applicants be attentive to their obligation to timely file for the required authorizations and thus make every effort to ensure that they act in accordance with the statutory directives in FPA section 305(b). The Commission would look unfavorably on FPA section 305(b) applications where an applicant has not been properly attentive to his/her obligation to file for the required authorization.

[3] *See* Public Law 106–102, sec. 737, 113 Stat. 1338, 1479 (1999).

[4] 18 CFR 45.2(b)(2).

[5] NOPR, 164 FERC ¶ 61,032 at P 6. *See also* 16 U.S.C. 825d(b)(2).

[6] Golden Spread Comments at 3.

[7] *See* 16 U.S.C. 825d(c)(1), (2)(a).

[8] NOPR, 164 FERC ¶ 61,032 at PP 7–9.

[9] EEI Comments at 4 (quoting NOPR, 164 FERC ¶ 61,032 at P 9).

[10] *Id.*

[11] We note that the public utilities whose officers and directors are subject to the statutory directive in section 305(b) to file, as regulated entities themselves subject to the requirements of the FPA, and should make every effort to ensure that their officers and directors, in turn, act in accordance with the statutory directives in FPA section 305(b).

[12] 16 U.S.C. 825d(b)(1).

C. Supplemental Applications or Notices of Change for Positions Pre-Authorized Under § 45.9

1. Proposal

12. The Commission proposed in the NOPR to revise §§ 45.4 and 45.5 of its regulations to clarify that supplemental applications and notices of change need not be filed in the case of a person already authorized to hold interlocks identified in § 45.9(a) who may assume new or different positions that are still among those identified by § 45.9(a). The Commission stated that such changes in positions among related public utilities are already reported in the annual Form No. 561s, and separate filings under § 45.4 or § 45.5 are unnecessary. The NOPR specifically stated that the holder of interlocking officer and director positions must file a notice of change when he/she no longer holds any interlocking positions within the scope of the statute and regulations because no longer holding any interlocking positions would constitute a ''material or substantial change.'' [13]

2. Comments

13. EEI, Golden Spread, Just Energy, National Grid, NRECA, and NRG all support the Commission's proposed revisions to §§ 45.4 and 45.5.

14. EEI asks the Commission to add two points to its proposal to revise §§ 45.4 and 45.5. First, EEI asks for clarification that the Commission ''means a notice is required only when the officer or director resigns or withdraws from all pre-authorized interlocking officer and director positions, not just from one such position, as that would comport with the logic of the changes the Commission is adopting as to subsection 45.5(b).'' [14] EEI asserts that ''the Commission should specify that public utility officers and directors who are pre-approved under the holding company provisions at subsection 45.9(a) do not need to file 'notice of change' reports when they resign, but rather can rely on updates to their annual filings by removing the companies from which they have resigned during the previous year.'' [15]

15. Second, EEI also asks the Commission to specify that § 45.9(c) does not require an additional informational report in the case of new or different interlocking positions within a holding company system for an individual that has already filed a § 45.9 informational report.[16] EEI asserts that existing public utility officers and directors pre-approved under § 45.9(a) are not applicants as that term is used in § 45.5; therefore, they are not required to file applications at the Commission, only informational reports.[17]

16. Golden Spread asks the Commission to consider making an additional edit to § 45.5(b) to change the requirement for filing a notice of change (*e.g.,* for a withdrawal, or failure of reelection or appointment) from a ''within 30 days'' requirement to a ''within 60 days'' requirement, stating that even when good faith efforts are made to learn of changes from affected officers and directors, it can take beyond a full month to learn of changes.[18]

17. Just Energy recommends the Commission adopt a number of clarifying edits to §§ 45.4(c) and 45.9(a)(3) and (b). In § 45.4(c), Just Energy proposes that the Commission describe interlocking positions that ''qualify for automatic authorization pursuant'' to § 45.9(a), as opposed to positions that ''are identified'' in § 45.9(a). Just Energy suggests that, in § 45.9(a)(3), the Commission authorize interlocking positions of an officer or director of more than one public utility where such officer or director is already authorized under this part to hold positions as officer or director of those ''or any other public utilities'' where the interlock involves affiliated public utilities. Just Energy's proposed amendment to § 45.9(b) would create a new paragraph (b)(2) that states that a person is ''exempt from filing an informational report pursuant to [section] 45.4.''

18. Just Energy also states that it supports the proposal that officers and directors do not need to file a notice of change when they leave some but not other positions within a corporate family, and instead report interlock changes among affiliates in the applicable Form No. 561. Just Energy accordingly recommends additional amendments to amended § 45.5(b) to state that a notice of change under this section would not be required if the only change to be reported is ''a resignation or withdrawal from fewer than all positions held between or among affiliated public utilities, a reelection or reappointment to a position that was previously authorized,'' or holding a different or additional interlocking position ''that would qualify for automatic authorization pursuant to'' § 45.9(a). Just Energy states that its proposed amendments address the Commission's clarification regarding partial resignations and harmonize § 45.5 with the proposed amendments regarding appointments with affiliated entities.[19]

3. Commission Determination

19. We adopt the NOPR's proposed revisions to §§ 45.4 and 45.5 of the Commission's regulations to state that supplemental applications and notices of change need not be filed in the case of a person already authorized to hold interlocks identified in § 45.9(a) who may assume new or different positions that are still among those identified by § 45.9(a), with certain clarifications and amendments discussed below.

20. In response to EEI, we clarify that the change to § 45.5(b) adopted in this final rule means that, in the case of interlocking positions that are identified in § 45.9(a), a notice of change now need only be filed when the officer or director resigns or withdraws as an officer or director from *all* previously held interlocking officer and director positions. When he/she resigns from only one position out of several interlocking positions for which he/she received authorization pursuant to § 45.9, he/she need only include this information in the annual Form No. 561.

21. We also clarify in response to EEI that § 45.9(c) does not require an additional informational report when an officer or director has a new or different interlocking position within a holding company system compared to what was reported when he/she originally filed an informational report under § 45.9. Instead, he/she need only include the new or different interlocking position(s) in the annual Form No. 561.

22. We agree with Golden Spread's proposal to alter the timing of the notice of change filing requirement from 30 days to within 60 days of the triggering event. We think this change is reasonable because 30 days may be too short a period to comply with the regulation, and allowing for 60 days may result in more accurate filings. We therefore amend § 45.5(b) to state that the filing of a notice of change shall be made within 60 days.

23. We adopt Just Energy's proposed amendments to §§ 45.4(c), 45.9(a)(3) and (b), and 45.5(b). We find that the amendments proposed by Just Energy more clearly state the revisions adopted by this final rule.

[13] NOPR, 164 FERC ¶ 61,032 at P 10.

[14] EEI Comments at 7.

[15] *Id.* at 9–10.

[16] *Id.* at 7.

[17] *Id.* at 10.

[18] Golden Spread Comments at 4.

[19] Just Energy Comments at 6–7.

D. Public Utilities Within a Holding Company That Do Not Have Directors and Officers

1. Proposal

24. In the NOPR, the Commission recognized the growing complexity of corporate structures. Thus, the Commission proposed to revise § 45.8(c)(1) of its regulations to state that applicants under part 45 do not need to list in their applications those public utilities that do not have officers or directors.[20]

2. Comments

25. EEI, Golden Spread, and NRG support the Commission's proposed revision to § 45.8(c)(1). Golden Spread ''agrees that if such structures exist and do not have officers and directors, such information would be extraneous.'' [21] NRECA states that it has no position on the Commission's proposal; it acknowledges the growing complexity of corporate structures ''but does not appreciate why that trend warrants reducing the information in these applications.'' [22] NRECA requests that the Commission explain in more detail the regulatory burden that will be relieved and the information that will be lost by the proposed change.[23]

3. Commission Determination

26. We adopt the NOPR's proposed revisions to § 45.8(c)(1) of the Commission's regulations to state that applicants under part 45 do not need to list in their applications those public utilities that do not have officers or directors. While we are not aware of any applications that have been filed where a company does not have any officers or any directors, we understand from EEI that such companies do exist.[24]

27. In response to Golden Spread and NRECA, we are not aware that any material information would be lost by making this change. We expect the universe of companies that do not have any officers or directors to be small, as it is still atypical for a company to have neither officers nor directors. We also note that, under § 45.2(a), the obligation to make the appropriate filings extends to any person elected or appointed to perform executive duties or functions similar to those ordinarily performed by presidents, vice presidents, directors and others.[25] This pre-existing requirement, which the Commission has not proposed to change, should ensure that the change adopted above will not materially affect the Commission's oversight of jurisdictional interlocking positions.

E. Corporate Relationships Within the Scope of Automatic Authorizations

1. Proposal

28. In the NOPR, the Commission proposed to revise § 45.9 of its regulations to add the word ''person'' when defining the corporate relationships within the scope of the automatic authorizations addressed in § 45.9. The Commission recognized that public utilities can be owned not just by a corporate entity but by a natural person, and that the regulations should reflect this possibility.[26]

2. Comments

29. EEI, Golden Spread, and NRECA support the Commission's proposed revision to § 45.9. Golden Spread adds that it thinks this proposed change does not apply to cooperative governance structures.

3. Commission Determination

30. We adopt the proposed revision to § 45.9 of the Commission's regulations to add the word ''person'' when defining the corporate relationships within the scope of the automatic authorizations addressed in § 45.9. Given that some public utilities can be and are now owned by natural persons, a change in the regulations to reflect this development is warranted.[27]

F. Removal of § 46.2(b)

1. Proposal

31. The Commission proposed in the NOPR to update its regulations in part 46 to remove § 46.2(b), because the definitions were rendered obsolete as a result of the enactment of the Energy Policy Act of 2005 and the concurrent repeal of the Public Utility Holding Company Act of 1935 (PUHCA 1935).[28] The Commission noted in the NOPR that § 46.2(b) currently references the definition of ''holding company system'' and ''registered holding company system'' in PUHCA 1935.[29] However, the Energy Policy Act of 2005 repealed PUHCA 1935.[30] Thus, the Commission proposed to remove § 46.2(b). The Commission also proposed to update part 46 to change ''Rural Electrification Administration'' to ''Rural Utilities Service'' to reflect the name change of that organization.[31]

2. Comments

32. EEI, Golden Spread, and NRECA all support the removal of § 46.2(b) and the update of part 46 to change ''Rural Electrification Administration'' to ''Rural Utilities Service.''

3. Commission Determination

33. We adopt the proposed removal of § 46.2(b) from the Commission's regulations, as it is now outdated, and we update part 46 of the Commission's regulations to change ''Rural Electrification Administration'' to ''Rural Utilities Service'' to reflect the change in name of that organization.

G. Additional Issues Raised by Commenters

1. Amending § 45.1(a)(3)

a. Comments

34. EEI requests that the Commission amend § 45.1(a)(3) of its regulations by changing the closing phrase ''a public utility'' to ''such public utility,'' as stated in the opening sentence of FPA section 305(b)(1). EEI asserts that this change to the regulations would align the regulations with the statute, and it would recognize that Congress intended to require approval for interlocking director and officer positions between a utility and an electrical supplier only when the supplier supplies equipment to the utility involved, not just to other utilities. EEI also states that this change also would conform the part 45 regulations with one another.[32]

b. Commission Determination

35. We adopt EEI's suggested amendment to § 45.1(a)(3) of the Commission's regulations by changing the closing phrase ''a public utility'' to ''such public utility.'' We agree with EEI that this change will better align the regulations with the statute, and recognize that Congress intended to require approval for interlocking director and officer positions between a utility and an electrical supplier only when the supplier supplies electrical equipment to the utility involved, and not just to any utility.

[20] NOPR, 164 FERC ¶ 61,032 at P 11.

[21] Golden Spread Comments at 4.

[22] NRECA Comments at 2.

[23] *Id.*

[24] *See* Edison Electric Institute Comments, Docket No. AD12–6–002 (Nov. 28, 2016).

[25] 18 CFR 45.2(a).

[26] NOPR, 164 FERC ¶ 61,032 at P 12.

[27] In response to Golden Spread, we do not envision a cooperative governance structure where a rural electric cooperative is owned by its customers/ratepayers to fall within the scope of this rule. *See generally Wolverine Power Supply Cooperative, Inc.,* 93 FERC ¶ 61,328, at 62,119 (2000), *reh'g denied,* 94 FERC ¶ 61,178, at 61,616 (2001).

[28] *See* Public Law 109–58, sec. 1261–77, 119 Stat. 594, 972–78 (2005).

[29] 16 U.S.C. 79a *et seq.*

[30] Public Law 109–58, sec.1263, 119 Stat. 594, 974 (2005).

[31] NOPR, 164 FERC ¶ 61,032 at P 13.

[32] EEI Comments at 9.

2. Definition of Electrical Equipment

a. Comments

36. EEI asks the Commission to modify its current definition of ''electrical equipment.'' EEI asserts that the definition of electrical equipment has been inappropriately construed too broadly in some cases. EEI requests that the Commission delete from the current § 46.2(f) definition the footnoted cross-reference to the Uniform System of Accounts and clarify that the definition applies to both parts 45 and 46 of the Commission's regulations. EEI asserts that the current definition found in § 46.2(f) is straightforward,[33] and that the cross-reference to the Uniform System of Accounts has resulted in the term electrical equipment being defined to include common business equipment such as computers, calculators, and sprinklers.[34]

b. Commission Determination

37. We decline to delete from the current § 46.2(f) definition of electrical equipment the footnoted cross-reference to the Uniform System of Accounts. We disagree that the cross-reference to the Uniform System of Accounts results in a definition of electrical equipment that is too broad. In this regard, we note that, in establishing the definition of electrical equipment in § 46.2(f), the Commission stated that the footnoted reference to the Commission's Uniform System of Accounts was ''a guide only,'' acknowledging that certain items found in the accounts listed are clearly not ''electrical equipment'' within the scope of § 46.2(f).[35] We find that the footnoted reference to the Uniform System of Accounts continues to provide useful guidance to aid the industry as well as the Commission in determining what does and does not constitute electrical equipment under part 46, and thus should be retained.

38. We do clarify that, as necessary, the Commission, in evaluating applications and reporting under part 45, will continue to look to § 46.2(f) and the footnoted reference to the Uniform System of Accounts for guidance in determining what constitutes electrical equipment under part 45.[36]

3. Blanket Authorizations for Companies Without Captive Customers

a. Comments

39. EEI, EPSA, Just Energy, and NRG ask the Commission to create a blanket authorization for interlock holders at companies within holding company systems without captive customers.

i. EEI

40. EEI requests that the Commission revisit the need for interlocking directorate applications and reporting to cover officers and directors who hold positions involving, within a holding company system, multiple companies that do not have captive customers, such as exempt wholesale generators and qualifying facilities, or positions involving such companies and their securities underwriters[37] or their electrical equipment suppliers.[38]

ii. EPSA

41. EPSA requests that the Commission consider granting a blanket authorization to public utilities without any captive customers, to allow individuals to concurrently hold positions as an officer or director of more than one public utility within the corporate holding company, or positions of officer or director of a public utility and a company supplying electrical equipment to a public utility within the corporate holding company.[39]

42. EPSA argues that this category of public utility, which includes independent power producers that are structured as merchant sellers of power only, are incapable of and do not pose a danger of imposing excessive charges or allocating unreasonable costs to customers, flouting state regulation in any way, or harming customers through a general lack of economy of management, operation, inefficiency, or inadequacy of services. EPSA asserts that, with independent entities, any mismanagement or uneconomic transactions are not passed on to customers, but are borne exclusively by shareholders. EPSA proposes that blanket authorizations be granted solely to those utilities on an intra-holding company basis.[40]

43. EPSA suggests that, to provide oversight to companies eligible for its proposed blanket authorization, ''an entity with market-based rate authority and previously granted a blanket authorization for interlocking positions within its holding company could declare in its triennial market-based rate authorization filings that its holding company structure remains fully independent, and therefore that entity continues to pose no threat of harm to captive customers as a result of affiliate abuse concerns and, as such, does not pose a threat to pass on rate increases driven by affiliate contracts or contracts between independent companies with a common set of officers or directors.''[41] EPSA also compares its requested blanket authorization to blanket authorizations under FPA section 203.[42]

44. EPSA asserts that granting blanket authorization to intra-holding company independent power producers and marketers without captive customers is a logical outgrowth of the NOPR and is consistent with the NOPR's intent, and would serve to reduce regulatory burdens and modernize these regulations to better reflect the modern state of the electricity generation and sales landscape.[43] EPSA also suggests that the Commission could issue a supplemental notice in order to broaden the scope of the NOPR to implement EPSA's proposed changes in the final rule.[44]

iii. Just Energy

45. Just Energy requests that the Commission grant blanket authorizations to public utilities that are not franchised utilities and are not affiliated with a franchised utility. Under Just Energy's proposal, officers and directors of such public utilities and their affiliates would not be required to seek prior authorization, but would disclose all appointments and changes on their annual Form No. 561.[45]

iv. NRG

46. NRG asks the Commission to issue a ''narrow and discrete'' blanket authorization for individuals holding officer positions in affiliated entities all under the same holding company structure without any captive customers, regardless of whether those positions are with public utilities, electrical equipment supply companies, or fuel supply companies.[46] Under this proposal, the individual would be able to hold positions in such entities

[33] *Id.* at 11 (citing 18 CFR 46.2(f)).

[34] *Id.*

[35] *Public Utility Filing Requirement and Requirements for Persons Holding Interlocking Positions; Order Issuing Final Regulations,* 45 FR 23413, at 23415–16 (Apr. 7, 1980), FERC Stats. & Regs. ¶ 30,140, at 30,984 (1980).

[36] *See, e.g., Barry Lawson Williams,* 134 FERC ¶ 61,183, at P 10 (2011).

[37] *But see* 16 U.S.C. 825d(b)(2).

[38] EEI Comments at 10.

[39] EPSA Comments at 2.

[40] *Id.* at 3.

[41] *Id.* at 4.

[42] *Id.* at 4–5 (citing *Transactions Subject to FPA Section 203,* Order No. 669, 113 FERC ¶ 61,315, at P 57 (2005), *order on reh'g,* Order No. 669–A, 115 FERC ¶ 61,097, *order on reh'g,* Order No. 669–B, 116 FERC ¶ 61,076 (2006)).

[43] *Id.* at 8–9.

[44] *Id.* at 9.

[45] Just Energy Comments at 5–6.

[46] We note that an interlock involving the latter, *i.e.,* fuel supply companies, would not be a jurisdictional interlock under FPA section 305(b) requiring a filing.

without any filing requirements (either a prior-notice filing or the annual Form No. 561).[47]

47. Like EPSA, NRG compares its requested blanket authorization to section 203 blanket authorizations.[48] NRG states that allowing blanket waivers in the interlock context would still allow the Commission to rigorously police for the conduct that concerned Congress in 1935 (that companies under common control were entering into above market contracts and passing through those costs to retail customers), meet the plain language of the statute, and reduce the paperwork burden and regulatory burdens on regulated entities.[49]

48. Although NRG asserts that the Commission could provide for a blanket authorization as requested with no further notice because it is a ''logical outgrowth'' of the NOPR, NRG suggests that the Commission could also issue, out of an abundance of caution, a supplemental notice describing the blanket authorization.[50]

b. Commission Determination

49. We decline to create a blanket authorization for persons holding interlocking positions between affiliated companies without any captive customers. The current requirements impose minimal burdens, and the commenters have not made a sufficient case for granting their requested relief of a blanket authorization.

50. The burden that would be avoided by a blanket authorization for individuals serving as officers or directors at multiple companies in a holding company system is minimal. Currently, in such scenarios, each individual must file only once—and then only a relatively minor submittal—for authorization (under § 45.9 of the Commission's regulations), and then each individual needs to file only an annual report pursuant to FPA section 305(c) each April 30 thereafter,[51] which describes any changes in his/her positions among the companies in the holding company system.

51. In response to EPSA and NRG's comparison of an interlock blanket authorization to blanket authorizations in the FPA section 203 context, we note that, although the Commission implemented blanket authorizations in the section 203 context, it was done in response to the Energy Policy Act of 2005, which revised FPA section 203 by adding FPA section 203(a)(5), which required the Commission to adopt procedures for the expeditious consideration of applications under that section.[52] No similar circumstances exist here.

4. Online Submission Process/Database for Interlock Filings

a. Comments

52. Golden Spread and NRECA filed comments requesting the creation of an online submission process/database for interlock filings. Golden Spread requests that the Commission consider moving the interlocking directorate application, updating/supplementing, termination process, and annual Form No. 561 to an online submission process. Golden Spread argues that the current system is paper intensive and an online system could streamline compliance associated with parts 45 and 46 and would create an opportunity for more robust relational databases wherein the Commission would be better able to track compliance with its interlocking directorate program.[53] Golden Spread and NRECA state that an online submission process/database would reduce regulatory burdens.[54]

b. Commission Determination

53. We support modernizing our systems and processes. However, we will not propose a new submission process or database in this proceeding, but may consider the creation of an online process/database in the future.

5. Temporary Appointments

a. Comments

54. Just Energy states that it is not uncommon for market participants to have to appoint, remove, or reappoint personnel to officer positions to accommodate routine business needs that are not always foreseeable or permanent. For example, Just Energy states that a company may need to make a person an officer in order to have signature authority for a transaction, or when someone is on medical leave. Just Energy requests that these administrative, ministerial, or temporary appointments not require any Commission approval or reporting, arguing that they do not pose the kinds of threats contemplated by Congress when it adopted section FPA 305(b), and are burdensome to both the Commission and to public utilities.[55]

b. Commission Determination

55. We acknowledge that an exemption from the filing requirements for certain temporary appointments to interlocking positions reflects the reality of the world, where a position may be unexpectedly left vacant due to death, illness, etc. and a company must quickly appoint someone to temporarily fill the now-vacant position on an ''acting'' basis. We therefore find that a person seeking to hold an interlocking position covered by § 45.2 that would otherwise require an automatic authorization filing under § 45.9 may be appointed to fill the vacant position temporarily, for 90 days or less, without the necessity of seeking Commission approval or of reporting in, for example, Form No. 561. To implement this change, we add a new paragraph (c) to § 45.1, as well as additional language to § 45.9(b) that exempts a person holding a temporary interlocking position pursuant to the new § 45.1(c) from the requirement to submit an informational report.

56. We note that this temporary appointment exemption would, in practice, apply only in a narrow set of circumstances—where a person *who has never held any interlock before* is temporarily appointed to a position at an affiliate company. For example, a person serving as an officer of Utility A could be temporarily appointed as an officer of affiliated Utility B, which is part of the same holding company as Utility A, without the necessity of Commission approval or a reporting requirement such as the annual Form No. 561. In this example, if this person had previously been authorized to hold a non-temporary interlock between two or more affiliated utilities, this exemption for temporary positions would not be necessary; the person would already have been required to have made an initial automatic authorization filing under § 45.9, and would only need to include this new appointment in his/her annual Form No. 561.

57. Finally, we note that a person cannot be re-appointed for multiple 90-day periods to the same interlocking position and still consider it a temporary position that continues to be exempt from the automatic authorization requirements. Under such circumstances, the individual who seeks to hold a position for more than 90 days

[47] NRG Comments at 5–6.

[48] *Id.* at 6 (citing *Blanket Authorization Under FPA Section 203,* Order No. 708, 122 FERC ¶ 61,156 (2008)).

[49] *Id.*

[50] *Id.* at 6–7.

[51] Even if we were to grant the requested relief under FPA section 305(b), that would not relieve the persons holding such interlocks from the separate requirement to make an annual filing, the Form No. 561, under FPA section 305(c).

[52] Public Law 109–58, sec. 1289, 119 Stat. 594, 982 (2005); Order No. 669, 113 FERC ¶ 61,315 at PP 55–57.

[53] Golden Spread Comments at 5.

[54] *Id.*; NRECA Comments at 3.

[55] Just Energy Comments at 6.

must seek the necessary authorization pursuant to the Commission's regulations.

6. Cost Estimates for Informational Filings and Notices of Change

a. Comments

58. Just Energy, in asserting that it is costly and burdensome for individuals, and in many cases their employers, to comply with the rules as written, states that the Commission's estimates that informational filings cost $632.00 each, and that notices of change cost $19.25, are too low. In support, Just Energy asserts that: (1) Each filing must be customized to the individual; (2) the officer or director must verify the reportable positions; (3) a notary may be required for the attestation; (4) a corporate secretary may have to pull information on positions held to verify the submission; (5) corporate structure information may need to be pulled to verify that the ownership chain qualifies for an informational filing; (6) someone reviews the materials; (7) someone makes revisions to the filing; (8) someone collects signatures; and (9) someone makes the filing.[56]

b. Commission Determination

59. We disagree that we have underestimated the costs of informational filings and notices of change. We note that the cost estimates stated in the NOPR and in this final rule are estimates of average costs. While the costs of some informational filings and notices of change will be higher than the stated averages, some will also be less than the stated averages.

III. Information Collection Statement

60. The collection of information contained in this final rule is subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act (PRA).[57] The PRA requires each federal agency to seek and obtain OMB approval before undertaking a collection of information directed to 10 or more persons or contained in a rule of general applicability. OMB's regulations[58] require approval of certain information collection requirements imposed by agency rules. Upon approval of a collection of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of an agency rule will not be penalized for failing to respond to the collection of information unless the collection of information displays a valid OMB control number.

61. The revisions enacted by this final rule would clarify and update the requirements[59] for those seeking and holding interlocking positions. The Commission anticipates that the revisions, once effective, would reduce regulatory burdens. The Commission will submit the reporting requirements to OMB for its review and approval under section 3507(d) of the Paperwork Reduction Act.[60]

62. While the Commission expects that the regulatory revisions herein will reduce the burdens on affected entities, the Commission nonetheless solicits public comments regarding the accuracy of the burden and cost estimates below.

63. *Burden Estimate:*[61] The estimated burden and cost for the requirements contained in this final rule follow.

FERC FORM NO. 520

[Application for authority to hold interlocking directorate positions]

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response[62]	Total annual burden hours (total annual cost)	Cost per respondent ($)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Full	16	1	16	50 hrs.; $3,950	800 hrs.; $63,200	3,950
Informational	500	1	500	8 hrs.; $632	4,000 hrs.; $316,000	632
Notice of Change	100	1	100	0.25 hrs.; $19.75	25 hrs.; $1,975	19.75
Total					4,825 hrs.; $381,175	

Title: FERC–520 (Application for Authority to Hold Interlocking Directorate Positions).

OMB Control No.: 1902–0083.

Abstract: The FPA, as amended, mandates federal oversight and approval of certain electric corporate activities to ensure that neither public nor private interests are adversely affected. Accordingly, the Commission's regulations prescribe related information filing requirements to achieve this goal. Such filing requirements are found in 18 CFR parts 45 and 46.

Overview of the Data Collection. FERC–520 provides information related to complex electric corporate activities, in particular, the holding of interlocking positions, and thereby serves to safeguard public and private interests, as the FPA requires.

FERC–520 is divided into two types of applications: full and informational. The full application, as specified in 18 CFR 45.8, implements the FPA requirement under section 305(b) that it is unlawful for any person to concurrently hold the positions of officer or director of more than one public utility; or a public utility and a financial institution that is authorized to underwrite or participate in the marketing of public utility securities; or a public utility and an electrical equipment supplier to such public utility, unless authorized by the Commission. In order to obtain authorization, an applicant must demonstrate that neither public nor private interests will be adversely affected by the holding of the positions. The full application provides the Commission with information about any interlocking position for which the applicant seeks authorization including, but not limited to, a description of

[56] *Id.* at 3, n.4.

[57] 44 U.S.C. 3507(d).

[58] 5 CFR part 1320.

[59] 18 CFR parts 45, 46.

[60] 44 U.S.C. 3507(d).

[61] ''Burden'' is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[62] The Commission staff thinks that the average respondent for this collection is similarly situated to the Commission, in terms of salary plus benefits. Based upon FERC's 2018 annual average (for salary plus benefits) of $164,820, the average hourly cost is $79/hour.

duties and the estimated time devoted to the position.

An informational (abbreviated) application, as specified in 18 CFR 45.9, allows an applicant to receive automatic authorization for an interlocked position upon receipt of the filing by the Commission. The informational application applies only to those individuals who seek authorization as: (1) An officer or director of two or more public utilities where the same holding company owns, directly or indirectly, that percentage of each utility's stock (of whatever class or classes) which is required by each utility's by-laws to elect directors; (2) an officer or director of two public utilities, if one utility is owned, wholly or in part, by the other and, as its primary business, owns or operates transmission or generation facilities to provide transmission service or electric power for sale to its owners; or (3) an officer or director of more than one public utility, if such person is already authorized under part 45 to hold different positions as officer or director of those utilities where the interlock involves affiliated public utilities.

FERC–520 also includes the requirement to file a notice of change if there are new positions or changes to the positions held. The Commission is revising its requirements and, among other things, will no longer require a notice of change when a person is merely changing positions within a holding company system. This change is expected to reduce the number of filed notices of change by 50 percent annually (from 200 filings to 100 filings) and to reduce the corresponding total burden.

Type of Respondents: Individuals who plan to concurrently become or concurrently are officers or directors of public utilities and of certain other entities must request authorization to hold such interlocking positions by submitting a FERC–520.

Internal Review: The Commission has reviewed the information collection requirements and has determined that certain changes are needed and that the remaining requirements are necessary. These requirements conform to the Commission's need for efficient information collection, communication, and management within the energy industry. The Commission has specific, objective support for the burden estimates associated with the information collection requirements. Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 [Attention: Ellen Brown, Office of the Executive Director], email: *DataClearance@ferc.gov,* Phone: (202) 502–8663, fax: (202) 273–0873. Comments concerning the collection of information and the associated burden estimate(s) may also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 [Attention: Desk Officer for the Federal Energy Regulatory Commission]. Due to security concerns, comments should be sent electronically to the following email address: *oira_submission@omb.eop.gov.* Please refer to FERC–520, OMB Control No. 1902–0083 in your submission.

IV. Environmental Analysis

64. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[63] We conclude that neither an Environmental Assessment nor an Environmental Impact Statement is required for this final rule under § 380.4(a) of the Commission's regulations, which provides a categorical exemption for actions under section 305 of the FPA relating to interlocking directorates.[64]

V. Regulatory Flexibility Act

65. The Regulatory Flexibility Act of 1980 (RFA)[65] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. The Small Business Administration's (SBA) Office of Size Standards develops the numerical definition of a small entity.[66] These standards are provided in the SBA regulations at 13 CFR 121.201.[67]

66. This final rule will apply to those individuals seeking to hold and those currently holding interlocking positions. In order to obtain authorization, an applicant must demonstrate that neither public nor private interests will be adversely affected by the holding of the interlocking positions.

67. There are an estimated 16 respondents who could file full applications over the course of a year, who would provide one response annually with an estimated time commitment of 50 hours per response, and a resulting estimated cost of $3,950.00 per respondent. There are an estimated 500 respondents who could file informational applications over the course of a year, who would provide one response annually with an estimated time commitment of 8 hours per response, and a resulting estimated cost of $632.00 per respondent. In addition, there are an estimated 100 respondents who could file a notice of change annually with an estimated time commitment of 0.25 hours, and a resulting cost of $19.75 per respondent. Therefore the average annual cost for each of the 616 respondents is $618.79. That cost is not significant. More importantly, this final rule reduces industry cost by eliminating the need for the filing of some notices of change.

68. The Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

VI. Document Availability

69. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street NE, Room 2A, Washington, DC 20426.

70. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

71. User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

VII. Effective Date and Congressional Notification

72. These regulations are effective May 3, 2019. The Commission has determined that this rule is not a ''major rule'' as defined in section 351 of the

[63] Regulations Implementing the National Environmental Policy Act of 1969, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987).

[64] 18 CFR 380.4(a)(16).

[65] 5 U.S.C. 601–612.

[66] 13 CFR 121.101.

[67] 13 CFR 121.201. *See also* U.S. Small Business Administration, *Table of Small Business Size Standards Matched to North American Industry Classification System Codes* (effective Feb. 26, 2016), *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

Small Business Regulatory Enforcement Fairness Act of 1996.

List of Subjects

18 CFR Part 45

Electric utilities, Reporting and recordkeeping requirements.

18 CFR Part 46

Antitrust, Electric utilities, Holding companies, Reporting and recordkeeping requirements.

By the Commission.

Issued: February 21, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

In consideration of the foregoing, the Commission amends parts 45 and 46, chapter I, title 18, *Code of Federal Regulations,* as follows:

PART 45—APPLICATION FOR AUTHORITY TO HOLD INTERLOCKING POSITIONS

■ 1. The authority citation for part 45 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; 3 CFR 142.

■ 2. Amend § 45.1 by revising paragraph (a)(3) and adding paragraph (c) to read as follows:

§ 45.1 Applicability; who must file.

(a) * * *

(3) Officer or director of a public utility and of any company supplying electrical equipment to such public utility.

* * * * *

(c) Notwithstanding paragraphs (a) and (b) of this section, any person may temporarily hold an interlocking position described in § 45.2 for no more than 90 days within a twelve-month period without applying for Commission authorization under § 45.8 and without complying with the requirements for authorization under § 45.9.

■ 3. Amend § 45.2 by adding paragraph (d) to read as follows:

§ 45.2 Positions requiring authorization.

* * * * *

(d) A person that holds or proposes to hold an interlocking position as officer or director of a public utility and of a corporation described by paragraph (b)(2) of this section shall not require authorization to hold such positions in the following circumstances—

(1) The person does not participate in any deliberations or decisions of the public utility regarding the selection of the bank, trust company, banking association, or firm to underwrite or participate in the marketing of securities of the public utility, if the person serves as an officer or director of a bank, trust company, banking association, or firm that is under consideration in the deliberation process;

(2) The bank, trust company, banking association, or firm of which the person is an officer or director does not engage in the underwriting of, or participate in the marketing of, securities of the public utility of which the person holds the position of officer or director;

(3) The public utility for which the person serves or proposes to serve as an officer or director selects underwriters by competitive procedures; or

(4) The issuance of securities of the public utility for which the person serves or proposes to serve as an officer or director has been approved by all Federal and State regulatory agencies having jurisdiction over the issuance.

■ 4. Revise § 45.3(a) to read as follows:

§ 45.3 Timing of filing application.

(a) The holding of positions within the purview of section 305(b) of the Act shall be unlawful unless the holding shall have been authorized by order of the Commission. Nothing in this part shall be construed as authorizing the holding of positions within the purview of section 305(b) of the Act prior to order of the Commission on application therefor. Applications must be filed and authorization must be granted prior to holding any interlocking positions within the purview of section 305(b) of the Act; the Commission will consider late-filed applications on a case-by-case basis. The term ''holding,'' as used in this part, shall mean acting as, serving as, voting as, or otherwise performing or assuming the duties and responsibilities of officer or director within the purview of section 305(b) of the Act.

* * * * *

■ 5. Amend § 45.4 by adding paragraph (c) to read as follows:

§ 45.4 Supplemental applications.

* * * * *

(c) *Changes in interlocking positions within the scope of § 45.9.* Notwithstanding paragraphs (a) and (b) of this section, in the case of interlocking positions that qualify for automatic authorization pursuant to § 45.9(a), a filing under this section will not be required if the only changes to be reported are holding different or additional interlocking positions that would qualify for automatic authorization pursuant to § 45.9(a).

■ 6. Revise § 45.5(b) to read as follows:

§ 45.5 Supplemental information.

* * * * *

(b) *Notice of changes.* In the event of the applicant's resignation, withdrawal, or failure of reelection or appointment in respect to any of the positions for which authorization has been granted by the Commission, or in the event of any other material or substantial change therein, the applicant shall, within 60 days after any such change occurs, give notice thereof to the Commission setting forth the position, corporation, and date of termination therewith, or other material or substantial change. In the case of interlocking positions that qualify for automatic authorization pursuant to § 45.9(a), a notice of change under this section will not be required if the only change to be reported is a resignation or withdrawal from fewer than all positions held between or among affiliated public utilities, a reelection or reappointment to a position that was previously authorized, or holding a different or additional interlocking position that would qualify for automatic authorization pursuant to § 45.9(a).

* * * * *

■ 7. Revise § 45.8(c)(1) to read as follows:

§ 45.8 Contents of application.

* * * * *

(c) * * *

(1) Name of utility, unless said utility does not have officers or directors.

* * * * *

■ 8. Revise § 45.9(a)(1) and (3) and (b) to read as follows:

§ 45.9 Automatic authorization of certain interlocking positions.

(a) * * *

(1) Officer or director of one or more other public utilities if the same holding company or person owns, directly or indirectly, that percentage of each utility's stock (of whatever class or classes) which is required by each utility's by-laws to elect directors;

* * * * *

(3) Officer or director of more than one public utility, if such officer or director is already authorized under this part to hold positions as officer or director of those or any other public utilities where the interlock involves affiliated public utilities.

(b) *Conditions of authorization.* (1) As a condition of authorization, any person eligible to seek authorization to hold interlocking positions under this section must submit, prior to performing or assuming the duties and responsibilities of the position, an informational report

in accordance with paragraph (c) of this section, unless that person:

(i) Is already authorized to hold interlocking positions of the type governed by this section;

(ii) Is exempt from filing an informational report pursuant to § 45.4; or

(iii) Will hold a temporary interlocking position pursuant to § 45.1(c).

(2) The Commission will consider failures to timely file the informational report on a case-by-case basis.

* * * * *

PART 46—PUBLIC UTILITY FILING REQUIREMENTS AND FILING REQUIREMENTS FOR PERSONS HOLDING INTERLOCKING POSITIONS

■ 9. The authority citation for part 46 continues to read as follows:

Authority: 16 U.S.C. 792–828c; 16 U.S.C. 2601–2645; 42 U.S.C. 7101–7352; E.O. 12009, 3 CFR 142.

■ 10. Amend § 46.2 by revising paragraph (a), removing and reserving paragraph (b), and revising paragraphs (c) and (e) to read as follows:

§ 46.2 Definitions.

* * * * *

(a) *Public utility* has the same meaning as in section 201(e) of the Federal Power Act. Such term does not include any rural electric cooperative which is regulated by the Rural Utilities Service of the Department of Agriculture or any other entities covered in section 201(f) of the Federal Power Act.

* * * * *

(c) *Purchaser* means any individual or corporation within the meaning of section 3 of the Federal Power Act who purchases electric energy from a public utility. Such term does not include the United States or any agency or instrumentality of the United States or any rural electric cooperative which is regulated by the Rural Utilities Service of the Department of Agriculture.

* * * * *

(e) *Entity* means any firm, company, or organization including any corporation, joint-stock company, partnership, association, business trust, organized group of persons, whether incorporated or not, or a receiver or receivers, trustee or trustees of any of the foregoing. Such term does not include *municipality* as defined in section 3 of the Federal Power Act and does not include any Federal, State, or local government agencies or any rural electric cooperative which is regulated by the Rural Utilities Service of the Department of Agriculture.

* * * * *

[FR Doc. 2019–03419 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9850]

RIN 1545–BM28

Utility Allowance Submetering

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that amend the utility allowance regulations concerning the low-income housing credit under section 42 of the Internal Revenue Code (Code). These final regulations extend the principles of the current submetering rules. The current rules address situations in which a building owner purchases a utility from a utility company and then separately charges the tenants for the utility. In those situations, if the utility costs paid by a tenant are based on actual consumption in the tenant's submetered, rent-restricted unit and if certain other requirements are satisfied, then the charges for the utility are treated as paid by the tenant directly to the utility company, even though the payment passes through the building owner. The final regulations extend these principles and apply to situations in which a building owner sells to tenants energy that is produced from a renewable source and that the owner did not purchase from or through a local utility company. The final regulations affect owners of low-income housing projects that claim the credit, the tenants in those low-income housing projects, and the State and local housing credit agencies that administer the credit.

DATES:

Effective date: These final regulations are effective on March 4, 2019.

Applicability date: For dates of applicability, see § 1.42–12(a)(5).

FOR FURTHER INFORMATION CONTACT: Dillon Taylor, (202) 317–4137 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On March 3, 2016, the Department of the Treasury (Treasury Department) and the IRS published in the **Federal Register** (81 FR 11104) final and temporary regulations (TD 9755) that amended § 1.42–10 of the Income Tax Regulations. The final regulations in TD 9755 clarified the circumstances in which utility costs paid by a tenant based on actual consumption in a submetered, rent-restricted unit are treated as paid by the tenant directly to the utility company and not to the building owner. In such a case, for purposes of section 42, the tenant's payments to the owner for the utilities are not treated as payments of gross rent, and the rent that the owner might otherwise have collected for the unit is reduced by an amount that is called a ''utility allowance.'' The temporary regulations extended the principles of those final regulations to situations in which a building owner sold to tenants energy that was produced from a renewable source and that the owner had not purchased from or through a local utility company.

In the same issue of the **Federal Register** (81 FR 11160), the Treasury Department and the IRS published a notice of proposed rulemaking (REG–123867–14) (the proposed regulations). The text of the proposed regulations incorporated by cross-reference the text of the temporary regulations. The Treasury Department and the IRS received written and electronic comments responding to the proposed regulations. No requests for a public hearing were made, and no public hearing was held.

After consideration of all the comments, the proposed regulations are adopted as amended by this Treasury Decision.

Summary of Comments and Explanation of Provisions

The temporary regulations in TD 9755 applied the submetering principles to energy that the building owner sold to tenants if the energy was ''produced from a renewable source'' and if the owner had acquired it from the renewable source without the intervention of a local utility company. Qualification for this submetering treatment, however, depended on the charges to the tenants for this energy being comparable to local utility rates. That is, under the temporary regulations, to the extent that tenants consumed this energy, the rate charged by the building owner could not exceed the rate at which the local utility company would have charged the tenants if they had instead acquired the energy from that company.

A commenter requested that the final regulations clarify how a building

owner may demonstrate that the rate that the owner charges tenants for renewable energy satisfies this requirement (the evidentiary issue). In addition, if there are multiple local utility rates that the tenants might have been charged (possibly from multiple utility companies), the commenter asked for clarification as to which rate or rates should be taken into account in determining whether the owner's charges to the tenants qualify (the reference-rate issue).

The final regulations resolve both of these issues. Addressing the reference-rate issue, the final regulations require that the rate that the owner charges must not exceed the highest rate at which the tenants might have obtained energy from a local utility company. This criterion has several advantages over alternatives. For example, it is easily administrable (as compared, for example, with a requirement that the owner's rate not exceed the ''most typical rate'' in the community). Also, the criterion protects an owner's qualifying rate from being disqualified by the introduction of new rates in the community (as might be the case, for example, if the reference for the criterion were the average or median of local rates).

Regarding the evidentiary issue, in determining the acceptability of the rate that a building owner charges tenants, the owner may rely on the rates published by local utility companies.

The temporary regulations in TD 9755 provide that, for purposes of qualifying for submetering treatment, energy is ''produced from a renewable source'' if it is energy that is produced from energy property described in section 48; energy that is produced from a facility described in section 45(d)(1), (2), (3), (4), (6), (9), or (11); or energy that is described in guidance published for this purpose in the Internal Revenue Bulletin. Sections 45 and 48 of the Code determine whether a taxpayer is entitled to certain energy-related credits. A commenter requested that the final regulations clarify the extent to which these cross-references to ''energy property'' and ''facility'' incorporate the various requirements for earning those credits.

The final regulations clarify that the building owner need not own the source from which the utility is produced and need not qualify for, or receive, any credit under section 45 or 48 associated with the source. Indeed, energy may qualify as ''produced from a renewable resource'' even if potential entitlement to credits under these Code sections has expired. Thus, the final regulations clarify that they refer to ''energy property'' and ''facility'' as a means of describing certain types of production of renewable energy but that they do not also incorporate any other criteria from those Code sections.

Under section 42(g)(1) and (2), a residential unit may qualify as a low-income unit only if it is ''rent-restricted.'' The amount that qualifies as restricted rent is determined based on the assumption that most utilities are generally covered by that rent. *See* H.R. Conf. Rep. 99–841, at II–94 (1986). For that reason, if the tenant pays for a utility directly, the rent that the owner may require from the tenant is reduced. The amount of this reduction is called a ''utility allowance.'' *See* section 42(g)(2)(B)(ii) and § 1.42–10(a). Language in the preamble of TD 9755 states that utility costs paid by a tenant based on actual consumption in a submetered, rent-restricted unit are treated as paid by the tenant directly to the utility and thus do not count against the maximum rent that the building owner can charge. Referencing this language, one commenter requested that the final regulations clarify whether a building owner of a submetered building is required to reduce its maximum gross rents by the amount of a utility allowance. Because § 1.42–10(e) treats a tenant in a submetered, rent-restricted unit as having paid for a utility directly and not by or through the owner of the building, the proper treatment of the tenant's submetered utility payments is the same as if the tenant had made those payments directly to the utility company—(1) Although the payments pass through the building owner, they are not treated for purposes of the rent restriction as if they were payments of rent; and (2) The amount of rent that the owner might otherwise have demanded from the tenant is reduced by the amount of an applicable utility allowance.

Special Analyses

This regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations. Therefore, a regulatory impact assessment is not required. It has also been determined that the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply because the regulations do not impose a collection of information on small entities. Pursuant to section 7805(f) of the Internal Revenue Code, this proposed rule preceding these final regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business and no comments were received.

Drafting Information

The principal author of this regulation is James W. Rider, formerly of the Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the Treasury Department and the IRS participated in its development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by removing the entry for § 1.42–10T to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Sections 1.42–6, 1.42–8, 1.42–9, 1.42–10, 1.42–11, and 1.42–12, also issued under 26 U.S.C. 42(n).

§ 1.42–0T [Amended]

■ **Par. 2.** Section 1.42–0T is amended by removing the entries for § 1.42–10T.

■ **Par. 3.** Section 1.42–10 is amended by:

■ 1. Revising paragraph (e)(1)(i) introductory text.

■ 2. Revising paragraph (e)(1)(i)(B).

■ 3. Adding paragraphs (e)(1)(i)(C) and (D).

■ 4. Revising paragraph (e)(1)(iv)(B).

The revisions and additions read as follows:

§ 1.42–10 Utility allowances.

* * * * *

(e) * * *

(1) * * *

(i) The utility consumed in the unit is described in paragraph (e)(1)(i)(A) or (e)(1)(i)(B) of this section;

* * * * *

(B) The utility is not purchased from or through a local utility company and is produced from a renewable source (within the meaning of paragraph (e)(1)(i)(C) of this section).

(C) For purposes of paragraph (e)(1)(i)(B) of this section, a utility is produced from a renewable source if—

(*1*) It is energy that is produced from energy property described in section 48;

(*2*) It is energy that is produced from a facility described in section 45(d)(1), (2), (3), (4), (6), (9), or (11); or

(*3*) It is a utility that is described in guidance published for this purpose in the Internal Revenue Bulletin (see § 601.601(d)(2)(ii) of this chapter).

(D) Determinations under paragraphs (e)(1)(i)(C)(*1*) and (*2*) of this section take into account only the manner in which the energy is produced and not who owns the energy property or the facility or whether the applicability of relevant portions of sections 45 and 48 has expired.

* * * * *

(iv) * * *

(B) To the extent that the utility consumed is described in paragraph (e)(1)(i)(B) of this section, the utility rate charged to the tenants of the unit does not exceed the highest rate that the tenants would have paid if they had obtained the utility from a local utility company. In determining whether a rate satisfies the preceding sentence, a building owner may rely on the rates published by local utility companies.

* * * * *

§ 1.42–10T [Removed]

■ **Par. 5.** Section 1.42–10T is removed.

■ **Par. 6.** Section 1.42–12 is amended by:

■ 1. Revising paragraph (a)(5)(i)(E).

■ 2. Revising paragraph (a)(5)(ii).

■ 3. Adding paragraph (a)(5)(iii).

The revisions and addition read as follows:

§ 1.42–12 Effective dates and transitional rules.

(a) * * *

(5) * * *

(i) * * *

(E) Section 1.42–10(e), except as provided in paragraph (a)(5)(iii) of this section.

(ii) Except as provided in paragraph (a)(5)(iii) of this section, a building owner may apply the provisions described in paragraphs (a)(5)(i)(A) through (E) of this section to the building owner's taxable years beginning before March 3, 2016. Otherwise, the utility allowance provisions that apply to those taxable years are contained in § 1.42–10, as contained in 26 CFR part 1, revised as of April 1, 2015.

(iii) The provisions in § 1.42–10(e)(1)(i) introductory text, (e)(1)(i)(B) through (D), and (e)(1)(iv)(B) apply to a building owner's taxable years beginning on or after March 4, 2019. A building owner, however, may apply these provisions to earlier taxable years. Otherwise, the submetering provisions that apply to taxable years beginning after March 3, 2016, and before March 4, 2019, are contained in § 1.42–10 and § 1.42–10T as contained in 26 CFR part 1 revised as of April 1, 2016. In addition, a building owner may apply those submetering provisions to taxable years beginning before March 3, 2016.

* * * * *

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: February 26, 2019.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2019–03827 Filed 2–27–19; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG–2018–0231]

RIN 1625–AA00, 1625–AA08, 1625–AA11, 1625–AA87

Removal of Regulated Navigation Areas, Safety Zones, Security Zones, and Special Local Regulations Within District 7

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is updating District 7 regulations to reflect the current status of identified regulated navigation areas, special local regulations, safety zones, and security zones within the District. This rule removes safety zones and special local regulations for rules where the enforcement period has expired or where the event is no longer held. This rule also removes special local regulations where the event no longer meets the criteria for a permitted event and is not suitable for coverage under a special local regulation in accordance with Coast Guard regulations.

DATES: This rule is effective April 3, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2018–0231 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: For information about this document, call or email Paul Lehmann, District Seven Prevention Division, U.S. Coast Guard; telephone 301–415–6796, email *Paul.D.Lehmann@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CATEX Criteria for Categorical Exclusion
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

This rulemaking project was identified as part of the Coast Guard's Regulatory Reform Task Force initiative. These District 7 field regulation changes were identified as part of the deregulation identification process required by Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs), Executive Order 13777 (Enforcing the Regulatory Reform Agenda Deregulatory Process), and associated guidance issued in 2017. This rule provides updates and clarifications to existing regulatory text in title 33 of the Code of Federal Regulations (CFR) parts 100 and 165.

This rule removes safety zones and special local regulations for regulations where the enforcement period has expired or where the event is no longer held. This rule also removes special local regulations where the event no longer meets the criteria for a permitted event and is not suitable for coverage under a special local regulation in accordance with 33 CFR 100.35. District 7 has determined that normal navigation rules cover the safety of participants and spectators at these events adequately. If a change in circumstance indicates that additional safety measures are necessary, the Coast Guard might choose to promulgate new regulations for safety zones at these events at that time.

The changes to 33 CFR part 100 are specifically authorized under 33 U.S.C. 1233, which vests the Commandant of the Coast Guard with authority to issue regulations to promote the safety of life on navigable waters during regattas or marine parades. The changes to 33 CFR part 165 are authorized under the general authority of 22 U.S.C. 1231, which grants the Secretary of the Department of Homeland Security broad authority to issue, amend, or repeal regulations necessary to implement 33 U.S.C. chapter 25, Ports and Waterways Safety Program. The Secretary has delegated rulemaking authority under 33 U.S.C. 1231 to the Commandant via Department of Homeland Security Delegation No. 0170.1.

The Coast Guard is issuing this rule without prior notice and opportunity to

comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking with respect to this rule because it is unnecessary to do so. All of the changes in this final rule involve only minor amendments to existing regulations that will not result in a substantive effect on the public.

III. Discussion of Rule

A. Removal of Temporary Regulations for Past Events

(1) Temporary Special Local Regulations

This rule removes the temporary special local regulations 33 CFR 100.T07–0110, 100.T07–0192, and 100.35T07–0297. As discussed in the preamble for each of the associated **Federal Register** documents implementing these temporary regulations and the corresponding regulatory text, these regulations were meant to be of limited duration. They remain in the CFR at this time because of drafting errors in the **DATES** section of each of the implementing final rules. ''Special Local Regulation; Low Country Splash, Wando River, Cooper River, and Charleston Harbor, Charleston, SC,'' 33 CFR 100.T07–0110, was meant to expire on May 24, 2014, at 9 a.m. at the conclusion of the 2014 Low Country Splash. ''Special Local Regulations; Beaufort Water Festival, Beaufort, SC,'' 33 CFR 100.T07–0192, was meant to expire on July 26, 2015, at 4 p.m. at the conclusion of the 2015 Beaufort Water Festival. ''Special Local Regulation, 50 Aniversario Balneario de Boqueron, Bahia de Boqueron; Boqueron, PR,'' 33 CFR 100.35T07–0297 was meant to expire on May 5, 2013, at 4 p.m. at the conclusion of the 50 Aniversario Balneario de Boqueron.

(2) Temporary Safety Zones

This rule removes the temporary safety zone regulations 33 CFR 165.T07–0040, 165.T07–0161, 165.T07–0320 and 165.T07–0347. As discussed in the preamble for each of the accompanying **Federal Register** documents implementing these regulations and the corresponding regulatory text, these regulations were meant to be of limited duration. They remain in the CFR at this time because of drafting errors in the **DATES** section of each of the implementing final rules. ''Safety Zone; Cooper River Bridge Run, Charleston, SC,'' 33 CFR 165.T07–0040, was meant to expire on March 28, 2015, at 10:30 a.m., at the conclusion of the 2015 Cooper River Bridge Run. ''Safety Zone; Xterra Swim, Myrtle Beach, SC,'' 33 CFR 165.T07–0161, was mean to expire on May 4, 2014, at 8:15 a.m., at the conclusion of the 2014 Xterra Swim. ''Safety Zone; Fourth of July Fireworks North Myrtle Beach, SC,'' 33 CFR 165.T07–0320, was meant to expire on July 4, 2016, at 10:00 p.m., at the conclusion of the fireworks show. ''Safety Zone; Fourth of July Fireworks Murrells Inlet, SC,'' 33 CFR 165.T07–0347, was meant to expire on July 4, 2016, at 10 p.m.

None of these regulations—temporary special local regulations or temporary safety zones—have been enforced past the intended expiration period.

B. Removal of Special Local Regulations for Events No Longer Held

This rule removes certain entries in the list of recurring special local regulations in Captain of the Port (COTP) Zones Miami and Key West found in the table to 33 CFR 100.701. The Coast Guard has looked into each of these events and has found no evidence to indicate that these events are still being held. The entries being removed from this list for COTP Miami are Rotary Club of Fort Lauderdale New River Raft Race, Red Bull Candola, West Palm Beach Triathlon, and West Palm Beach World Championship. The entries being removed from this list for COTP Key West are The Bogey, The Bacal, and Miami to Key Largo Sailboat Race.

C. Removal of Special Local Regulations for Events No Longer Permitted

This rule removes special local regulations in COTP Zone Key West where the events in question no longer meet the criteria for permitted events and, therefore, are not suitable for coverage under a special local regulation in accordance with 33 CFR 100.35. District 7 has determined that the safety of participants and spectators at these events can be adequately covered by the normal navigational rules. If a change in circumstances indicates that additional safety measures are necessary, the Coast Guard might decide at that time to promulgate regulations for safety zones for these events. The entries being removed from this list for COTP Key West in the table to 33 CFR 100.701 are Blessing of the Fleet, Wreckers Cup Races, Boot Key Harbor Christmas Boat Parade, Key Colony Beach Holiday Boat Parade, Key Largo Boat Parade, and Key West Lighted Boat Parade.

D. 33 CFR 165.778

The Coast Guard is removing paragraph (d) from 33 CFR 165.778 regarding the effective period of the security zone for the Port of Mayaguez. Paragraph (d) states the section had an effective period that ended April 29, 2009. Paragraph (d) conflicts with the effective information stated in the **DATES** section of the issuing final rule (74 FR 14046, March 30, 2009). This rule has continuing effect and did not cease being in effect after April 29, 2009.

IV. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on these statutes or Executive orders.

A. Regulatory Planning and Review

Executive Orders 13563 (Improving Regulation and Regulatory Review) and 12866 (Regulatory Planning and Review) direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs) directs agencies to reduce regulation and control regulatory costs and provides that ''for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through a budgeting process.''

The Office of Management and Budget (OMB) has not designated this rule a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, OMB has not reviewed it. OMB considers this rule to be an Executive Order 13771 deregulatory action. *See* the OMB Memorandum titled ''Guidance Implementing Executive Order 13771, titled 'Reducing Regulation and Controlling Regulatory Costs''' (April 5, 2017).

The Coast Guard is revising its regulations to provide updates and clarifications to existing regulatory text in title 33 of the Code of Federal Regulations (CFR) parts 100 and 165.

The revisions include the removal of temporary safety zones and special local regulations for past events, special local regulations for events no longer held and special local regulations for events no longer permitted. Normal navigation rules sufficiently cover the safety of participants and spectators at events that are no longer suitable for coverage under a special local regulation. This rule involves non-substantive changes and internal agency practices and procedures; it will not impose any additional costs on the public or the government. The qualitative benefit of the non-substantive changes is increased clarity of regulations. The increased clarity of the CFR is created by the removal of expired enforcement periods and the removal of events that are no longer held.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. This rule will not impose any impacts on any entities. This means that there will be no economic impacts on any entities. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

C. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this rule.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

D. Collection of Information

This rule does not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). This rule does not change any of the burdens in the collections currently approved by OMB.

E. Federalism and Indian Tribal Government

A rule has implications for federalism under Executive Order 13132 (Federalism) if it has a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1538, requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any 1 year. Although this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

G. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, and Commandant Instruction M16475.lD (COMDTINST M16475.1D), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f). Our determination is that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under the **ADDRESSES** section of this preamble.

This rule meets the criteria for categorical exclusion (CATEX) under paragraphs L54, L60, and L61 in Appendix A of DHS Directive 023–01. CATEX L54 pertains to promulgation of regulations that are editorial or procedural; CATEX L60 pertains to regulations for establishing, disestablishing, or changing Regulated Navigation Areas and security or safety zones; and CATEX L61 pertains to special local regulations issued in conjunction with a regatta or marine parade. This rule amends the Coast Guard District 7 field regulations by incorporating updates and clarifications to existing regulatory text in title 33 CFR parts 100 and 165. These changes generally pertain to removing certain obsolete special event regulations or clarifying the intended effective period of the security zone for the Port of Mayaguez (33 CFR 165.778).

The Coast Guard's Regulatory Reform Task Force Initiative identified these regulation changes, which are consistent with the Coast Guard's maritime safety and stewardship missions.

List of Subjects

33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons stated in the preamble, the Coast Guard amends 33 CFR parts 100 and 165 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 33 CFR 1.05–1.

§ 100.T07–0110 [Removed]

■ 2. Remove § 100.T07–0110

§ 100.T07–0192 [Removed]

■ 3. Remove § 100.T07–0192

§ 100.35T07–0297 [Removed]

■ 4. Remove § 100.35T07–0297

§ 100.701 [Amended]

■ 5. In § 100.701, amend the table to § 100.701 as follows:
■ a. Add the heading ''(a) COTP Zone Miami; Special Local Regulations'' before entry 1 at the top of the table.
■ b. Remove entries (a)1, 4, 6, and 9.
■ c. Redesignate entries (a)2, 3, 5, 7, 8, and 10 through 15 as entries (a)1 through 11.
■ d. Remove entries (c)1, 2, 4, 5, 6, 10, 11, 12, and 13.
■ e. Redesignate entries (c)3, 7, 8, and 9 as entries (c)1 through 4.

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 6. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

§ 165.T07–0040 [Removed]

■ 7. Remove § 165.T07–0040.

§ 165.T07–0161 [Removed]

■ 8. Remove § 165.T07–0161.

§ 165.T07–0320 [Removed]

■ 9. Remove § 165.T07–0320.

§ 165.T07–0347 [Removed]

■ 10. Remove § 165.T07–0347.

§ 165.778 [Amended]

■ 11. Amend § 165.778 by removing paragraph (d).

Dated: February 27, 2019.

Peter J. Brown,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 2019–03844 Filed 3–1–19; 8:45 a.m.]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0127]

RIN 1625–AA00

Safety Zone; Cumberland River, Kentucky

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters between mile marker 0.0 and mile marker 3.0 of the Cumberland River in Smithland, Kentucky. The safety zone is needed to protect personnel, vessels, and personal property from potential hazards created by vessel wake during a high water event. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective without actual notice from March 4, 2019 until March 15, 2019. For the purposes of enforcement, actual notice will be used from February 26, 2019 until March 4, 2019. This rule will be enforced from February 26, 2019 to March 15, 2019, unless the lower gauge at Smithland Lock and Dam falls below 50 feet, in which case the enforcement of this rule will be terminated.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0127 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST2 Dylan Caikowski, Marine Safety Unit Paducah, U.S. Coast Guard; telephone 270–442–1621 ext. 2120, email *STL-SMB-MSUPaducah-WWM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Ohio Valley
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this emergency safety zone by February 26, 2019 to ensure the safety of residents and the protection of personal property near the riverfront in Smithland, Kentucky during a high water event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because delaying the effective period will compromise the safety of residents, vessels, and personal property near the riverfront of Smithland, Kentucky during a high water event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Ohio Valley (COTP) has determined a safety zone is needed to protect personnel, vessels, and personal property from potential hazards created by vessel wake during a high water event.

IV. Discussion of the Rule

This rule establishes a safety zone from February 26, 2019 to March 15, 2019 or when the lower gauge at Smithland Lock and Dam falls below 50 feet, whichever occurs first. The safety zone will cover all navigable waters between mile marker 0.0 and mile marker 3.0 of the Cumberland River in Smithland, Kentucky. The duration of the zone is intended to protect personnel, vessels, and the personal property in these navigable waters during the high water event. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The COTP or a designated representative will inform the public through broadcast notices to mariners of any changes in the planned schedule.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not

been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, duration, and location of the safety zone. This safety zone will only be enforced for 18 days on a three-mile stretch of the Cumberland River near Smithland, Kentucky, while the area is experiencing a high water event. The enforcement of the zone will be terminated once the lower gauge at Smithland Lock and Dam falls below 50 feet, whichever occurs first. While entry is prohibited, vessels may request permission from the COTP or a designated representative to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone that will cover all navigable waters between mile marker 0.0 and mile marker 3.0 of the Cumberland River in Smithland, Kentucky. The safety zone is intended to protect personnel, vessels, and personal property in these navigable waters during a high water event. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034; 46 U.S.C. 70051; 33 CFR 1.05–1; 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0127 to read as follows:

§ 165.T08–0127 Safety Zone; Cumberland River, Smithland, KY.

(a) *Location.* The safety zone will encompass all waters of the Cumberland River between mile marker 0.0 and mile marker 3.0.

(b) *Effective dates.* This section is effective without actual notice from March 4, 2019 until March 15, 2019. For the purposes of enforcement, actual notice will be used from February 26, 2019 until March 4, 2019.

(c) *Period of enforcement.* This section will be enforced from February 26, 2019 to March 15, 2019, unless the lower gauge at Smithland Lock and Dam falls below 50 feet, in which case the enforcement of this rule will be terminated.

(d) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this safety zone is prohibited unless authorized by the Captain of the Port Sector Ohio Valley (COTP) or a designated representative.

(2) Persons or vessels desiring entry to or passage through the safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM channel 16 or by telephone at 502–779–5400.

(3) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(e) *Informational broadcasts.* The COTP or a designated representative will inform the public through broadcast notices to mariners of any changes in the planned schedule.

Dated: February 26, 2019.

M.B. Zamperini,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2019–03832 Filed 3–1–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0713]

RIN 1625–AA00

Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is modifying the Navy Pier Southeast Safety Zone within the Chicago Harbor. This action is necessary to alleviate congestion near the Chicago Lock during regularly scheduled fireworks events. The current safety zone encompasses part of the lock restricting vessels during events. This rule allows the lock to remain in full operation during the fireworks display.

DATES: This rule is effective April 3, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2018–0713 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email LT John Ramos, Waterways Management Division, Marine Safety Unit Chicago, U.S. Coast Guard; telephone (630) 986–2155, email *D09-DG-MSUChicago-Waterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Captain of the Port (COTP) Lake Michigan is modifying the size of the established safety zone outlined in 33 CFR 165.931 (a) to allow for the Chicago Lock to remain open during fireworks displays. The current safety zone encompasses all waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53′26.5″ N, 087°35′26.5″ W; then south to 41°53′7.6″ N, 087°35′26.3″ W; then west to 41°53′7.6″ N, 087°36′23.2″ W; then north to 41°53′26.5″ N, 087°36′24.6″ W; then east back to the point of origin (NAD 83). The safety zone in this final rule still ensures a safe distance for spectators while allowing the Chicago Lock to remain open during the duration of the fireworks. The area in this final rule encompasses all waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53′23.3″ N, 087°36′04.5″ W; then south to 41°53′11.8″ N, 087°36′04.1″ W; then west to 41°53′12.1″ N, 087°35′40.5″ W; then north to 41°53′23.6″ N, 087°35′40.07″ W; then east back to the point of origin (NAD 83).

On September 13, 2018 the Coast Guard published a notice of proposed rulemaking (NPRM) in the **Federal Register** titled Safety Zone; Chicago Harbor, Navy Pier Southeast, Chicago, IL, 33 CFR part 165 (83 FR 46449).

Included in the NPRM was an invitation to make comments on the proposed regulatory action for the modification of the size of the Navy Pier Southeast Safety Zone. The Coast Guard received 14 comments during the comment period, which ended October 15, 2018.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP Lake Michigan has determined that modifying the preexisting safety zone will reduce congestion near the Chicago Lock. This rule would not significantly change the regulatory language found in 33 CFR 165.931. The change will only moderately reduce the size of the safety zone with updated coordinates, found in 33 CFR 165.931 (a). The purpose of this rule is to protect the safety of vessels and persons in the safety zone before, during, and after scheduled events while allowing the Chicago Lock to remain open for vessel traffic.

IV. Discussion of Comments, Changes, and the Rule

As noted above, The Coast Guard received fourteen (14) comments on our NPRM published September 13, 2018. There were ten (10) comments that supported modifying the size of the safety zone to allow the Chicago Lock and Dam to remain open, allowing vessels to proceed during the Fireworks Display. There were two (2) comments that were unrelated to the modification of the Safety Zone and two (2) comments that addressed congestion and the safety issues of modifying the size of the Safety Zone.

One of these comments misinterpreted the authority under which the safety zone is issued. The commenter refers to 50 U.S.C. 191 but that statute provides the authority for security zones. See, 33 CFR 165.9(c). As noted above in the ''Legal Authority and Need for Rule'' section, this rule is under authority in 33 U.S.C. 1231.

The other comment failed to comprehend that the safety zone in this final rule does allow vessel traffic to safely proceed through the Chicago Lock without entering the safety zone. The safety zone in this final rule was evaluated and we determined that the reduction in size could be accomplished safely while allowing the Chicago Lock to remain open for vessel traffic. Allowing the Lock to remain open alleviates vessel congestion that is also a safety concern.

After review, the Coast Guard amended this final rule by updating the coordinates outlined in the NPRM to take into account applicable comments and suggestions. The new safety zone will encompass all waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53′23.3″ N, 087°36′04.5″ W; then south to 41°53′11.8″ N, 087°36′04.1″ W; then west to 41°53′12.1″ N, 087°35′40.5″ W; then north to 41°53′23.6″ N, 087°35′40.07″ W; then east back to the point of origin (NAD 83).

This rule does reduce the size of the safety zone outlined in 33 CFR 165.931 (a), but the size of the new safety zone still ensures a safe distance for spectators as well as vessels entering and exiting the locks. These new coordinates will allow vessels transiting to and from the lock to proceed North or South, while still maintaining a safe distance from the Fireworks Display. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and, pursuant to OMB guidance, it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area for less than 1 hour during the scheduled events. Indeed, this action will allow for greater transit than the pre-existing safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard wants to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The Coast Guard has analyzed this rule under that Order and has determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we discuss the effects of this rule elsewhere in this preamble.

F. Environment

The Coast Guard has analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone enforced intermittently, and for no longer than the time necessary to protect vessels and persons during scheduled Fireworks Displays. It is categorically excluded from further review under L60 (a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this reduction in size of a preexisting safety zone is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 165.931 by revising paragraph (a) to read as follows:

§ 165.931 Safety Zone, Chicago Harbor, Navy Pier Southeast, Chicago, IL.

(a) *Location.* The following area is a safety zone: The waters of Lake Michigan within Chicago Harbor bounded by coordinates beginning at 41°53′23.3″ N, 087°36′04.5″ W; then south to 41°53′11.8″ N, 087°36′04.1″ W; then west to 41°53′12.1″ N, 087°35′40.5″ W; then north to 41°53′23.6″ N, 087°35′40.7″ W; then east back to the point of origin (NAD 83).

* * * * *

Dated: February 26, 2019.

Thomas J. Stuhlreyer,

Captain, U.S. Coast Guard, Captain of the Port, Lake Michigan.

[FR Doc. 2019–03777 Filed 3–1–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0128]

RIN 1625–AA87

Security Zone; Corpus Christi Ship Channel, Corpus Christi, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard establishes two security zones. One of the zones is a temporary fixed security zone for the receiving facility's mooring basin while the Liquefied Natural Gas Carrier (LNGC) MARAN GAS MYSTRAS is moored at the facility. The other zone is a moving security zone encompassing all navigable waters within a 500-yard radius around the LNGC MARAN GAS MYSTRAS while the vessel transits with cargo in the La Quinta Channel and Corpus Christi Ship Channel in Corpus Christi, TX. The security zones are needed to protect personnel, vessels, and the marine environment from potential hazards created by Liquified Natural Gase (LNG) cargo aboard the vessel. Entry of vessels or persons into these zones is prohibited unless specifically authorized by the Captain of the Port Sector Corpus Christi.

DATES: This rule is effective without actual notice from March 4, 2019 until March 15, 2019. For the purposes of enforcement, actual notice will be used from February 28, 2019 until March 4, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2019–0128 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Kevin Kyles, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5125, email *Kevin.L.Kyles@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Corpus Christi
DHS Department of Homeland Security
FR Federal Register
LNGC Liquefied Natural Gas Carrier
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish these security zones by February 26, 2019 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to provide for the security of the vessel.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Corpus Christi (COTP) has determined that potential hazards associated with Liquefied Natural Gas Carrier (LNGC) MARAN GAS MYSTRAS between February 28, 2019 and March 15, 2019 will be a security concern while the vessel is moored at the receiving facility and within a 500-yard radius of the vessel while the vessel is loaded with cargo.

IV. Discussion of the Rule

This rule establishes two security zones around LNGC MARAN GAS MYSTRAS from February 28, 2019 through March 15, 2019. A fixed security zone will be in effect in the mooring basin bound by 27°52′53.38″ N, 097°16′20.66″ W on the northern shoreline; thence to 27°52′45.58″ N, 097°16′19.60″ W; thence to 27°52′38.55″ N, 097°15′45.56″ W; thence to 27°52′49.30″ N, 097°15′45.44″ W; thence west along the shoreline to 27°52′53.38″ N, 097°16′20.66″ W, while LNGC MARAN GAS MYSTRAS is moored. A moving security zone will cover all navigable waters within a 500-yard radius of the LNGC MARAN GAS MYSTRAS while the vessel transits outbound with cargo through the La Quinta Channel and Corpus Christi Ship Channel. No vessel or person will be permitted to enter the security zones without obtaining permission from the COTP or a designated representative.

Entry into these security zones is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Corpus Christi. Persons or vessels desiring to enter or pass through the zones must request permission from the COTP or a designated representative on VHF–FM channel 16 or by telephone at 361–939–0450. If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative. The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs) of the enforcement times and dates for these security zones.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, duration, and location of the security zone. This rule will impact a small designated area of the Corpus Christi Ship Channel and La Quinta Channel while the vessel is moored at the receiving facility and during the vessel's transit while loaded with cargo. Moreover, the Coast Guard will issue BNMs via VHF–FM marine channel 16 about the zones and the rule allows vessels to seek permission to enter the zones.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary moving security zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary fixed security zone while LNGC MARAN GAS MYSTRAS is moored at the receiving facility mooring basin bound by 27°52′53.38″ N, 097°16′20.66″ W on the northern shoreline; thence to 27°52′45.58″ N, 097°16′19.60″ W; thence to 27°52′38.55″ N, 097°15′45.56″ W; thence to 27°52′49.30″ N, 097°15′45.44″ W; thence west along the shoreline to 27°52′53.38″ N, 097°16′20.66″ W, and a temporary moving security zone while the vessel transits with cargo within the La Quinta Channel and Corpus Christi Ship Channel, that will prohibit entry within 500-yard radius of LNGC MARAN GAS MYSTRAS. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 is amended to read as follows:

Authority: 46 U.S.C. 70034; 46 U.S.C. 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0128 to read as follows:

§ 165.T08–0128 Security Zone; Corpus Christi Ship Channel, Corpus Christi, TX.

(a) *Location.* The following areas are security zones:

(1) The mooring basin bound by 27°52′53.38″ N, 097°16′20.66″ W on the northern shoreline; thence to 27°52′45.58″ N, 097°16′19.60″ W; thence to 27°52′38.55″ N, 097°15′45.56″ W; thence to 27°52′49.30″ N, 097°15′45.44″ W; thence west along the shoreline to 27°52′53.38″ N, 097°16′20.66″ W, while LNGC MARAN GAS MYSTRAS is moored.

(2) All navigable waters encompassing a 500-yard radius around the Liquefied Natural Gas Carrier (LNGC) MARAN GAS MYSTRAS while transiting outbound with cargo through the La Quinta Channel and Corpus Christi Ship Channel.

(b) *Effective period.* This rule is effective without actual notice from March 4, 2019 until March 15, 2019. For the purposes of enforcement, actual notice will be used from February 28, 2019, until March 4, 2019.

(c) *Period of enforcement.* This section will be enforced from the time LNGC MARAN GAS MYSTRAS moors and while the vessel is transiting outbound through the La Quinta Channel and Corpus Christi Ship Channel from February 28, 2019 through March 15, 2019.

(d) *Regulations.* (1) The general regulations in § 165.33 of this part apply. Entry into these zones is prohibited unless authorized by the Captain of the Port Sector Corpus Christi (COTP) or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Corpus Christi.

(2) Persons or vessels desiring to enter or pass through the zones must request permission from the COTP or a designated representative on VHF–FM channel 16 or by telephone at 361–939–0450.

(3) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative.

(e) *Information broadcasts.* The COTP or a designated representative will inform the public through Broadcast Notices to Mariners (BNMs) of the enforcement times and date for these security zones.

Dated: February 27, 2019.

E.J. Gaynor,

Captain, U.S. Coast Guard, Captain of the Port Sector Corpus Christi.

[FR Doc. 2019–03833 Filed 3–1–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Parts 400, 401, 402, 403, 406, 410, 411, and 413

[Docket ID ED–2018–OCTAE–0129]

RIN 1830–AA23

Program Regulations Superseded by Reauthorizations of the Perkins Act

AGENCY: Office of Career, Technical, and Adult Education, Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary removes outdated and superseded regulations for eight programs in the State Vocational and Applied Technology Education Programs and National Discretionary Programs of Vocational Education as authorized under the Carl D. Perkins Vocational and Applied Technology Act of 1990 (Perkins II). The eight programs are: The Career, Technical and Applied Technology Education Programs—General Provisions, the Indian Vocational Education Program, the Native Hawaiian Vocational Education Program, the State Vocational and Applied Technology Education Program, the State-Administered Tech-Prep Education Program, the Tribally Controlled Postsecondary Vocational Institutions Program, the Vocational Education Research Program, and the National Center or Centers for Research in Vocational Education (the eight programs). These program regulations are outdated with the exception of certain regulations under the Indian Vocational Education Program.

DATES: These regulations are effective March 4, 2019.

FOR FURTHER INFORMATION CONTACT: Hugh Reid, U.S. Department of Education, 400 Maryland Avenue SW, Room 11114 PCP, Washington, DC 20202–2500. Telephone: (202) 245–7491. Email: *Hugh.Reid@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On February 24, 2017, President Trump signed Executive Order 13777, ''Enforcing the Regulatory Reform Agenda,'' which established a Federal policy ''to alleviate unnecessary regulatory burdens'' on the American people. Section 3(a) of the Executive Order directed each Federal agency to establish a regulatory reform task force, the duty of which is to evaluate existing regulations and ''make recommendations to the agency head regarding their repeal, replacement, or modification.'' Accordingly, the Secretary removes 34 CFR part 400, §§ 401.1–401.22 and 401.30 and 401.31, and parts 402, 403, 406, 410, 411 and 413, published in the **Federal Register** on August 14, 1992 (57 FR 36720) (Perkins 1992 Regulations), because they are outdated due to the reauthorization of the Perkins Act by subsequent reauthorizations and changes to the Perkins Act. The program regulations we are removing are:

The eight programs	Perkins 1992 regulations to be removed—34 CFR part(s)	Perkins II authorities 20 U.S.C.	Program type
Career, Technical, and Applied Technology Education Programs—General Provisions.	400 (57 FR 36724, Aug. 14, 1992) ..	20 U.S.C. 2301 *et seq.,* unless otherwise noted.	State-Administered.
Indian Vocational Education Program.	401.1–401.22 and 401.30 and 401.31 (57 FR 36730, Aug. 14, 1992).	20 U.S.C. 2313(b), unless otherwise noted.	National Discretionary.
Native Hawaiian Vocational Education Program.	402 (57 FR 36733, Aug. 14, 1992) ..	20 U.S.C. 2313(c), unless otherwise noted.	National Discretionary.
State Vocational and Applied Technology Education Program.	403 (57 FR 36735, Aug. 14, 1992) ..	20 U.S.C. 2301 *et seq.,* unless otherwise noted.	National Discretionary.

The eight programs	Perkins 1992 regulations to be removed—34 CFR part(s)	Perkins II authorities 20 U.S.C.	Program type
State-Administered Tech-Prep Education Program.	406 (57 FR 36763, Aug. 14, 1992) ..	20 U.S.C. 2394–2394e, unless otherwise noted.	State-Administered.
Tribally Controlled Postsecondary Vocational Institutions Program.	410 (57 FR 36773, Aug. 14, 1992) ..	20 U.S.C. 2397–2397h, unless otherwise noted.	National Discretionary.
Vocational Education Research Program.	411 (57 FR 36776, Aug. 14, 1992) ..	20 U.S.C. 2401 and 2402, unless otherwise noted.	National Discretionary.
National Center or Centers for Research in Vocational Education.	413 (57 FR 36780, Aug. 14, 1992) ..	20 U.S.C. 2404, unless otherwise noted.	National Discretionary.

The State-Administered Tech-Prep Education Program was not re-authorized in the Strengthening Career and Technical Education for the 21st Century Act (Perkins V) that was signed on July 31, 2018, and takes effect July 1, 2019. As such, we are removing the related regulations in 34 CFR part 406. Generally, the regulations for the other seven programs listed in the above chart are outdated due to the passage of the Carl D. Perkins Vocational and Technical Education Act of 1998 (Perkins III). These seven programs were updated in Perkins III and subsequently in the Carl D. Perkins Career and Technical Education Act of 2006 (Perkins IV) and Perkins V. However, the regulations related to these seven programs, have not been updated to reflect statutory changes in Perkins III–V, so we are removing those regulations. Although the statutory authority still exists for these seven program (not including The State-Administered Tech-Prep Education Program, which was not re-authorized), the regulations are outdated and do not reflect the most current statutory language. Therefore, we are removing those regulations, with the exception of 34 CFR 401.1 (formerly 401.23), which still applies to the Native American Career and Technical Education Program (NACTEP).

The requirements in 34 CFR 401.1 (formerly 401.23), regarding the Secretary's decision not to make an award under the Indian Vocational Education Program (now NACTEP) subject to a hearing, are not outdated. NACTEP is one of the successor programs to the Indian Vocational Education Program, and was established in Perkins IV.

34 CFR Part 400—Vocational and Applied Technology Education Programs—General Provisions

The purpose of the Vocational and Applied Technology Education Programs was to make the United States more competitive in the world economy by developing more fully the academic and occupational skills of all segments of the population, and the purpose would be achieved principally through concentrating resources on improving educational programs leading to academic and occupational skill competencies needed to work in a technologically advanced society.

This Perkins II regulation provided such general program provisions as the following:

(1) Purposes, which aligned with the purposes in Sec. 2 of Perkins II and were superseded by the purposes of Sec. 2 of Perkins III and subsequently by Sec. 2 of Perkins IV and Perkins V, respectively.

(2) Definitions, which aligned with the definitions in Secs. 232(d), 347, 371, 390, and 521 of Perkins II, and were superseded by the definitions in Sec. 3 of Perkins III; and subsequently by the definitions in Sec. 3 of Perkins IV, and Perkins V, respectively.

(3) Conditions for which funds under the Perkins Act were to be used for the joint funding of programs, which aligned with joint funding requirements in Sec. 511 of Perkins II, and were superseded by the joint funding requirements in Sec. 321 of Perkins III. Those requirements were subsequently superseded by Sec. 321 of Perkins IV, and Sec. 221 of Perkins V.

(4) Requirements for establishing the State Committee of Practitioners (Committee), aligned with Sec. 115 of Perkins II, which further clarified the State board convene the Committee on a regular basis to review, comment on, and propose revisions on a draft State proposal that the State board developed for a system of core standards and measures of performance for vocational programs. Perkins III did not include a requirement for establishing the Committee, and superseded that requirement in Sec. 113(b) indicating that each eligible agency, with input from eligible recipients, shall establish performance measures for a State. That requirement for establishing performance measures for a State with input from eligible recipients was subsequently superseded in Sec. 113(b) of Perkins IV, which was reauthorized in Perkins V.

(5) Governing student assistance, aligned with Sec. 507 of Perkins II regarding student assistance costs and was superseded by the requirement for student assistance costs in Sec. 325 of Perkins III. The requirement regarding student assistance costs was subsequently superseded by Sec. 324 of Perkins IV and Sec. 224 of Perkins V.

34 CFR Part 401—Indian Vocational Education Program

The purpose of the Indian Vocational Education Program was to provide financial assistance to projects that provide vocational education for the benefit of Indians. The regulations provided such general provisions as the definitions relative to the program, eligibility for a program award, and what activities could be funded. In addition, the regulations specified how one applied for an award, how the Secretary made the award, and what conditions must be met after the award. The regulations aligned with Sec. 103 of Perkins II, which provided directions to the Secretary to enter into grants with eligible applicants. Sec. 103 of Perkins II was updated by Perkins III, Sec. 116—Native American programs, under which grants were awarded under the Native American Vocational and Technical Education program. The requirements were subsequently updated by Perkins IV, Sec. 116—Native American programs, under which grants were awarded for NACTEP. Recently, Perkins V Sec. 116—Native American programs, also made minor revisions and updates to the NACTEP program. Although there have been minor revisions and updates under each reauthorization of the Perkins Act regarding some of the program requirements, the program purpose and administration supporting grants to improve CTE programs that benefit Native Americans has remained the same.

Title 34 CFR 401.1 (formerly 401.23) remains in effect, as it contains the requirements for when an applicant requests a hearing in response to the Secretary's decision not to make an award under the Indian Vocational

Education Program, as reauthorized (as NACTEP) under Sec. 116(b)(2) of Perkins V. The Secretary continues to implement the appeal process at the request of any applicant denied funding under the NACTEP competition in accordance with the procedures set forth in 34 CFR 401.1 (formerly 401.23) (see 83 FR 5076, 5079 at: *https://www.govinfo.gov/content/pkg/FR-2018-02-05/pdf/2018-02246.pdf*). In accordance with those procedures, any applicant denied funding has 30 calendar days to make a written request to the Secretary for a hearing to review the Secretary's decision (25 U.S.C. 5321(b)). We have also made the following technical revisions to § 401.1 (formerly § 401.23): (1) Replaced ''Indian Vocational Education Program'' with ''Native American Career and Technical Education Program'' in the title; (2) deleted reference to 34 CFR 401.2(a)(1), as this has been removed; and (3) replaced reference to ''Office of Vocational and Adult Education'' with ''Office of Career, Technical, and Adult Education''.

34 CFR Part 402—Native Hawaiian Vocational Education Program

The purpose of the Native Hawaiian Vocational Education Program was to provide financial assistance to projects responsible for vocational training and related activities for the benefit of native Hawaiians. This regulation provided such general provisions as the definitions relative to the program, eligibility for a program award, and what activities could be funded. In addition, the regulation specified how the Secretary made the award and what conditions must be met by a grantee after the award. This regulation aligned with Sec. 103 of Perkins II, which provided directions to the Secretary to enter into grants with eligible applicants. Sec. 103 of Perkins II was updated by Perkins III, Sec. 116—Native American programs, under which grants were awarded for the Native Hawaiian Vocational and Technical Education program. The requirement in Perkins III was subsequently updated by Sec. 116—Native American programs of Perkins IV, under which grants were awarded for the Native Hawaiian Career and Technical Education program, and was also superseded by Perkins V Sec. 116—Native American programs. Specifically, in Sec. 116(h) of Perkins III, and subsequently in Sec. 116(h) of Perkins IV and Perkins V, it was clarified that grants to plan, conduct, and administer programs, or portions thereof that are consistent with the purposes of section 116 of each Act, were for the benefit of Native Hawaiians.

34 CFR Part 403—State Vocational and Applied Technology Education Program

The purpose of the State Vocational and Applied Technology Education Program was for the Secretary to assist States, local educational agencies, postsecondary educational institutions, and other agencies and institutions to administer and conduct vocational education programs that were authorized by Perkins II. The requirements in the Perkins II regulations for the State Vocational and Applied Technology Education Program aligned with Title I—Vocational Education Assistance to the States in Perkins II, Part A—Allotment and Allocation and Part B—State Organizational and Planning Responsibilities. The Perkins II requirements were superseded by requirements under Perkins III, Title I—Vocational and Technical Education Assistance to the States—Part A—Allotment and Allocation, Part B—State Provisions and Part C—Local Provisions. The Perkins III requirements were subsequently superseded by requirements in Title I—Career and Technical Education Assistance to the States Part A—Allotment and Allocation, Part B—State Provisions and Part C—Local Provisions under both Perkins IV and Perkins V.

34 CFR Part 406—State-Administered Tech-Prep Education Program

The purposes of the Tech-Prep Education Program were to: (1) Plan for and develop four-year or six-year programs designed to provide a tech-prep education program leading to a two-year associate degree or certificate; and (2) plan and develop comprehensive links between secondary schools and postsecondary educational institutions. The requirements in the Perkins II regulations for the State-Administered Tech-Prep Education Program aligned with Title III, Part E—Tech-Prep Education. The Perkins II requirements were superseded by Title II—Tech-Prep Education under Perkins III and Perkins IV, respectively. Beginning in fiscal year 2010, Federal appropriations for Title II—Tech-Prep Education under Perkins IV ceased, and Perkins V did not authorize the program.

34 CFR Part 410—Tribally Controlled Postsecondary Vocational Institutions Program

The purpose of the Tribally Controlled Postsecondary Vocational Institutions Program was to provide grants for the operation and improvement of tribally controlled postsecondary vocational institutions in order to continue and expand educational opportunities for Indian students, and improve and expand the physical resources of those institutions. This regulation provided such general provisions as the definitions relative to the program, eligibility for a program award, and what activities could be funded. In addition, the regulation specified how the Secretary made the award and what conditions must be met after the award. This regulation aligned with Perkins II, Title III—Special Programs—Part H—Tribally Controlled Postsecondary Vocational Institutions. The requirements in Perkins II were updated by Perkins III, Sec. 117—Tribally Controlled Postsecondary Vocational Institutions, and subsequently updated by Sec. 117—Tribally Controlled Postsecondary Career and Technical Institutions of Perkins IV and Perkins V.

34 CFR Part 411—Vocational Education Research Program

The purpose of the Vocational Education Research Program was to: (1) Improve access to vocational educational programs for individuals with disabilities, individuals who were disadvantaged, men and women who were entering nontraditional occupations, adults who were in need of retraining, single parents, displaced homemakers, single pregnant women, individuals with limited English proficiency, and individuals who were incarcerated in correctional institutions; (2) support research and development activities that make the United States competitive in the world economy; (3) improve the competitive process by which research projects were awarded; (4) support the dissemination of findings of research related to Department-funded projects; and (5) support research activities that were readily applicable to the vocational education setting. This regulation indicated how the Secretary made an award, and was aligned with Sec. 402—Research Objectives and Sec. 403—Research Activities of Perkins II. The requirements in Perkins II was superseded by Perkins III, Sec. 114(c)—Research, Development, Dissemination, Evaluation and Assessment, which indicated that the Secretary through grants, contracts, or cooperative agreements, carry out research, development, dissemination, evaluation and assessment, capacity building, and technical assistance with regard to vocational and technical education programs. Sec. 114(c) of Perkins III was subsequently superseded by Perkins IV

and Perkins V, Sec. 114(c)—Single Plan for Research, Development, Dissemination, Evaluation, and Assessment. That section indicated that the Secretary may directly, or through grants, contracts, or cooperative agreements, carry out research, development, dissemination, evaluation and assessment, capacity building, and technical assistance with regard to career and technical education programs.

34 CFR Part 413—National Center or Centers for Research in Vocational Education

The purpose of the National Centers for Research in Vocational Education was to support: (1) Applied research; and (2) development and dissemination and training for vocational education. This regulation provided such general provisions as the definitions relative to the program, eligibility for a program award, and what activities could be funded. In addition, the regulation specified how the Secretary made the award and what conditions must be met after the award. The regulation aligned with Perkins II, Sec. 404—National Center or Centers for Research in Vocational Education. This Perkins II section was superseded by Sec. 114(c)(5) of Perkins III, which established the requirements for a national research center or centers, and was subsequently superseded by the requirements in Sec. 114(d)(4) of Perkins IV to establish a national research center. The Perkins IV, Sec. 114(d)(4) requirements were superseded by Sec. 114(d)(4) of Perkins V, which requires that the Secretary, after consultation with the Director of the Institute of Education Sciences, the Commissioner for Education Research, and the States, to award a grant, contract, or cooperative agreement, to carry out research activities.

Waiver of Proposed Rulemaking

Under the Administrative Procedures Act (5 U.S.C. 553) (APA), the Department generally offers interested parties the opportunity to comment on proposed regulations. However, the APA provides that an agency is not required to conduct notice-and-comment rulemaking when the agency, for good cause, finds that the requirement is impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(B) and (d)(3)). There is good cause to waive rulemaking in this case because this final regulatory action merely removes regulations that are superseded by statute and, therefore, outdated and unnecessary. This regulatory action adopts no new regulations and does not establish or affect substantive policy. Therefore, under 5 U.S.C. 553(b)(B), the Secretary has determined that proposed regulations are unnecessary, and, thus, waives notice and comment rulemaking.

The APA also requires that regulations be published at least 30 days before their effective date, unless the agency has good cause to implement its regulations sooner (5 U.S.C. 553(d)(3)). Because the final regulations merely reflect statutory changes and remove outdated or unnecessary regulatory provisions, the Secretary has good cause to waive the 30-day delay in the effective date of these regulatory changes under 5 U.S.C. 553(d)(3).

Executive Orders 12866, 13563, and 13771

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

Under Executive Order 13771, for each new regulation that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866, it must identify two deregulatory actions. For FY 2019, no regulations exceeding the agency's total incremental cost allowance will be permitted. These regulations are a deregulatory action under E.O. 13771 and therefore the two-for-one requirements of E.O. 13771 do not apply.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor their regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things, and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and

(5) Identify and assess available alternatives to direct regulation, including providing economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing this regulatory action only upon a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected the approach that maximizes net benefits. Based on the analysis that follows, the Department believes that these regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

Need for the Regulatory Action

This regulatory action is necessary to comply with Executive Order 13777 and to remove outdated and superseded regulations from the Code of Federal Regulations.

Analysis of Costs and Benefits

This regulatory action is a benefit to the public, grant recipients, and the Department as the action will remove any confusion that might be caused by maintaining outdated and superseded regulations in the CFR.

The Department has also analyzed the costs of this regulatory action and has determined that it will impose no additional costs. As detailed earlier, this regulatory action removes outdated and superseded regulations for eight programs.

Regulatory Flexibility Act Certification

Pursuant to 5 U.S.C. 601(2), the Regulatory Flexibility Act applies only to rules for which an agency publishes a general notice of proposed rulemaking. The Regulatory Flexibility Act does not apply to this rulemaking because there is good cause to waive notice and comment under 5 U.S.C. 553.

Paperwork Reduction Act of 1995

This rule does not contain any new information collection requirements. The information collection OMB Control Number 1830–0503, active during the Perkins II regulations with an annual cost to the Federal Government of $94,160, expired March 31, 2010. The only previously OMB-approved information collection under the Perkins II regulations that has been renewed, updated, and remains currently active is OMB Control Number 1830–0029. This information is used for the Perkins State Plan Guide and expires on September 30, 2019.

Intergovernmental Review

Some of these programs are subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at: *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

List of Subjects

34 CFR Part 400

Accounting, Administrative practice and procedure, Adult education, Aged, Agriculture, American Samoa, Bilingual education, Blind, Business and industry, Civil rights, Colleges and universities, Communications, Community development, Community facilities, Copyright, Credit, Cultural exchange programs, Educational facilities, Educational research, Education, Education of disadvantaged, Education of individuals with disabilities; Educational study programs, Electric power, Electric power rates, Electric utilities, Elementary and secondary education, Energy conservation, Equal educational opportunity, Federally affected areas, Government contracts, Grant programs, Grant programs—agriculture, Grant programs—business, Grant programs—communications, Grant programs—education, Grant programs—energy, Grant programs—health, Grant programs—housing and community development, Grant programs—social programs, Grants administration, Guam, Home improvement, Homeless, Hospitals, Housing, Human research subjects, Indians, Indians—education, Infants and children, Insurance, Intergovernmental relations, International organizations, Inventions and patents, Loan programs, Loan programs—social programs, Loan programs—agriculture, Loan programs—business, Loan programs—communications, Loan programs—energy, Loan programs—health, Loan programs—housing and community development, Manpower training programs, Migrant labor, Mortgage insurance, Nonprofit organizations, Northern Mariana Islands, Pacific Islands Trust Territories, Privacy, Renewable energy, Reporting and recordkeeping requirements, Rural areas, Scholarships and fellowships, School construction, Schools, Science and technology, Securities, Small businesses, State and local governments, Student aid, Teachers, Telecommunications, Telephone, Urban areas, Veterans, Virgin Islands, Vocational education, Vocational rehabilitation, Waste treatment and disposal, Water pollution control, Water resources, Water supply, Watersheds, Women.

34 CFR Part 401

Administrative practice and procedure, Grant programs—education, Grant programs—Indians, Indians—education, Reporting and recordkeeping requirements, Vocational education.

34 CFR Part 402

Grant programs—education, Hawaiian Natives, Reporting and recordkeeping requirements, Vocational education.

34 CFR Part 403

Business and industry, Colleges and universities, Elementary and secondary education, Grant programs—education, Prisoners, Reporting and recordkeeping requirements, Sex discrimination, Vocational education, Women.

34 CFR Part 406

Colleges and universities, Elementary and secondary education, Grant programs—education, Reporting and recordkeeping requirements, Vocational education.

34 CFR Part 410

Grant programs—education, Grant programs—Indians, Indians—education, Reporting and recordkeeping requirements, Vocational education.

34 CFR Part 411

Education of disadvantaged, Education of individuals with disabilities, Educational research, Grant programs—education, Prisoners, Reporting and recordkeeping requirements, Vocational education, Women.

34 CFR Part 413

Colleges and universities, Educational research, Grant programs—education, Reporting and recordkeeping requirements, Vocational education.

Dated: February 26, 2019.

Scott Stump,

Assistant Secretary for Career, Technical, and Adult Education.

For the reasons discussed in the preamble, and under the authority of section 414 of the Department of Education Organization Act, 20 U.S.C. 3474, and section 437 of the General Education Provisions Act (20 U.S.C. 1221e–3), the Secretary of Education amends chapter IV of title 34 of the Code of Federal Regulations as follows:

PART 400—[Removed and Reserved]

■ 1. Part 400 is removed and reserved.

PART 401—NATIVE AMERICAN CAREER AND TECHNICAL EDUCATION PROGRAM

■ 2. Revise the authority citation for part 401 to read as follows:

Authority: 20 U.S.C. 2313(b), 25 U.S.C. 5321.

■ 3. The heading of part 401 is revised to read as set forth above.

§ 401.1 [Removed]

■ 4. Remove § 401.1.

§ 401.23 [Redesignated as § 401.1 and Amended]

■ 5. Redesignate § 401.23 as § 401.1 and revise newly redesignated § 401.1 to read as follows:

§ 401.1 Is the Secretary's decision not to make an award under the Native American Career and Technical Education Program subject to a hearing?

(a) After receiving written notice from an authorized official of the Department that the Secretary will not award a grant or cooperative agreement to an eligible applicant, an Indian tribal organization has 30 calendar days to make a written request to the Secretary for a hearing to review the Secretary's decision.

(b) Within 10 business days of the Department's receipt of a hearing request, the Secretary designates a Department employee who is not assigned to the Office of Career, Technical, and Adult Education to serve as a hearing officer. The hearing officer conducts a hearing and issues a written decision within 75 calendar days of the Department's receipt of the hearing request. The hearing officer establishes rules for the conduct of the hearing. The hearing officer conducts the hearing solely on the basis of written submissions unless the officer determines, in accordance with standards in 34 CFR 81.6(b), that oral argument or testimony is necessary.

(c) The Secretary does not make any award under this part to an Indian tribal organization until the hearing officer issues a written decision on any appeal brought under this section.

§§ 401.2, 401.3, 401.4, and 401.5 [Removed and Reserved]

■ 6. Remove and reserve §§ 401.2, 401.3, 401.4, and 401.5.

§§ 401.10, 401.20, 401.21, 401.22, 401.30, and 401.31 [Removed]

■ 7. Remove §§ 401.10, 401.20, 401.21, 401.22, 401.30, and 401.31.

PART 402—[Removed and Reserved]

■ 8. Part 402 is removed and reserved.

PART 403—[Removed and Reserved]

■ 9. Part 403 is removed and reserved.

PART 406—[Removed and Reserved]

■ 10. Part 406 is removed and reserved.

PART 410—[Removed and Reserved]

■ 11. Part 410 is removed and reserved.

PART 411—[Removed and Reserved]

■ 12. Part 411 is removed and reserved.

PART 413—[Removed and Reserved]

■ 13. Part 413 is removed and reserved.

[FR Doc. 2019–03661 Filed 3–1–19; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2018–0771; FRL–9989–90–Region 1]

Air Plan Approval; Massachusetts; Air Emissions Inventory, Emissions Statements, Source Registration, and Emergency Episode Planning Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving State Implementation Plan (SIP) revisions submitted by the Commonwealth of Massachusetts. The revisions establish a 2011 base year emissions inventory, an emissions statement certification, revisions to an existing stationary source registration program, and requirements to be undertaken during air pollution emergencies. These SIP revisions were submitted to meet Clean Air Act requirements with respect to EPA's 1997 ozone, 2008 ozone, and 2010 SO_2 National Ambient Air Quality Standards. This action is being taken under the Clean Air Act.

DATES: This rule is effective on April 3, 2019.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R01–OAR–2018–0771. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Office of Ecosystem Protection, Air Quality Planning Unit, 5 Post Office Square, Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Bob McConnell, Environmental Engineer, Air Quality Planning Unit, Air Programs Branch (Mail Code OEP05–02), U.S. Environmental Protection Agency, Region 1, 5 Post Office Square, Suite 100, Boston, Massachusetts 02109–3912; (617) 918–1046; *mcconnell.robert@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. The term ''the Commonwealth'' refers to Massachusetts.

Table of Contents

I. Background and Purpose
II. Final Action
III. Incorporation by Reference
IV. Statutory and Executive Order Reviews

I. Background and Purpose

On December 4, 2018, (83 FR 62532), EPA published a notice of proposed rulemaking (NPRM) for the Commonwealth of Massachusetts. The NPRM proposed approval of a 2011 base year emissions inventory, an emissions statement certification, revisions to an existing stationary source registration program, and requirements to be undertaken during air pollution emergencies. The 2011 emissions inventory and the emissions statement

certification submittals were made to meet, in part, requirements for marginal nonattainment areas for the 2008 ozone national ambient air quality standard (NAAQS). The Commonwealth revised its stationary source registration program primarily to match the lead reporting threshold within 40 CFR part 51, subpart A. Massachusetts submitted its regulation governing procedures during air pollution emergencies to meet the infrastructure planning requirement found within section 110(a)(2)(G) of the Clean Air Act (CAA). Other specific requirements of the Commonwealth's SIP revisions and the rationale for our proposed action are explained in the NPRM and will not be restated here.

We did not receive any comments on our NPRM.

II. Final Action

EPA is approving SIP revisions submitted by the Commonwealth of Massachusetts representing a 2011 base year emissions inventory, an emissions statement certification, and revisions to 310 CMR 7.12, Source Registration. We are also converting our previous conditional approval of 310 CMR 8.00, The Prevention and/or Abatement of Air Pollution Episodes and Air Pollution Incident Emergencies, to a full approval.

III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of 310 CMR 7.12, Source Registration, and 310 CMR 8.00, The Prevention and/or Abatement of Air Pollution Episodes and Air Pollution Incident Emergencies, described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents generally available through *https://www.regulations.gov* and at the EPA Region 1 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

[1] 62 FR 27968 (May 22, 1997).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 3, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: February 20, 2019.

Deborah A. Szaro,

Acting Regional Administrator, EPA Region 1.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart W—Massachusetts

■ 2. In § 52.1120(c), amend the table by:
■ a. Revising the entry ''310 CMR 7.12'';
■ b. Removing the fourth entry for ''Regulations for Prevention And/or Abatement of Air Pollution Episode and Air Pollution Incident Emergencies'' and the entry ''310 CMR 8.02 and 8.03'';
and
■ c. Adding an entry ''310 CMR 8.00'' before the entry ''310 CMR 60.02''.

The revision and addition reads as follows:

§ 52.1120 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED MASSACHUSETTS REGULATIONS

State citation	Title/subject	State effective date	EPA approval date [1]	Explanations
*	*	*	*	*
310 CMR 7.12	U Source Registration	3/9/2018	3/4/2019, [Insert **Federal Register** citation].	Revisions made to existing requirements and procedures for emissions reporting.
*	*	*	*	*
310 CMR 8.00	The Prevention and/or Abatement of Air Pollution Episode and Air Pollution Incident Emergencies.	4/1/1994	3/4/2019, [Insert **Federal Register** citation].	Incorporates full version of 310 CMR 8.00 into the Massachusetts SIP, and converts conditional approval at § 52.1119(a)(5) to full approval.
*	*	*	*	*

[1] To determine the EPA effective date for a specific provision listed in this table, consult the **Federal Register** notice cited in this column for the particular provision.

* * * * *

■ 3. Section 52.1125 is amended by adding paragraph (e) to read as follows:

§ 52.1125 Emission inventories.

* * * * *

(e) The Commonwealth of Massachusetts submitted base year emission inventories representing emissions for calendar year 2011 for the Dukes county marginal 8-hour ozone nonattainment area on February 9, 2018, as a revision to the Massachusetts SIP. The 2011 base year emission inventory requirement of section 182(a)(1) of the Clean Air Act, as amended in 1990, has been satisfied for this area. The inventory consists of emission estimates of volatile organic compounds and nitrogen oxides, and applies to point, area, non-road mobile, on-road mobile and biogenic sources. The inventories were submitted as revisions to the Massachusetts SIP in partial fulfillment of obligations for nonattainment areas under EPA's 2008 8-hour ozone standard.

■ 4. Section 52.1129 is amended by adding paragraph (l) to read as follows:

§ 52.1129 Control strategy: Ozone.

* * * * *

(l) On February 9, 2018, Massachusetts submitted a certification that its air emissions reporting requirements applicable to stationary sources meet the emission statement requirements of section 182(a)(3)(B) of the Clean Air Act. The certification was submitted as a SIP revision in partial fulfillment of obligations for nonattainment areas under EPA's 2008 8-hour ozone standard.

■ 5. In § 52.1167, Table 52.1167 is amended by adding entries for state citations ''310 CMR 7.12'' and ''310 CMR 8'' in numerical order by state citation and date approved by EPA to read as follows:

§ 52.1167 EPA-approved Massachusetts State regulations.

* * * * *

TABLE 52.1167—EPA-APPROVED RULES AND REGULATIONS

[See Notes at end of table]

State citation	Title/subject	Date submitted by State	Date approved by EPA	**Federal Register** citation	52.1120(c)	Comments/unapproved sections
*	*	*	*	*	*	*
310 CMR 7.12	U Source Registration	5/10/2018	4/3/2019	[Insert **Federal Register** citation].		Revisions made to existing requirements and procedures for emissions reporting.
*	*	*	*	*	*	*
310 CMR 8	The Prevention and/or Abatement of Air Pollution Episode and Air Pollution Incident Emergencies.	2/9/2018	4/3/2019	[Insert **Federal Register** citation].		Incorporates full version of 310 CMR 8.00 into the Massachusetts SIP, and converts conditional approval at § 52.1119(a)(5) to full approval.
*	*	*	*	*	*	*

* * * * *

[FR Doc. 2019–03444 Filed 3–1–19; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RIN 0648–XG810

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure of the General category January fishery for 2019.

SUMMARY: NMFS closes the General category fishery for large medium and giant (*i.e.,* measuring 73 inches curved fork length or greater) Atlantic bluefin tuna (BFT) for the January subquota time period and thus until the General category reopens on June 1, 2019. The intent of this closure is to prevent overharvest of the available General category January 2019 BFT subquota of 100 metric tons (mt).

DATES: Effective 11:30 p.m., local time, February 28, 2019, through May 31, 2019.

FOR FURTHER INFORMATION CONTACT: Uriah Forest-Bulley, 978–675–2154, Sarah McLaughlin, 978–281–9260, or Larry Redd, 301–420–8503.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments.

NMFS is required, under § 635.28(a)(1), to file a closure notice with the Office of the Federal Register for publication when a BFT quota (or subquota) is reached or is projected to be reached. On and after the effective date and time of such notification, for the remainder of the fishing year or for a specified period as indicated in the notification, retaining, possessing, or landing BFT under that quota category is prohibited until the opening of the subsequent quota period or until such date as specified in the notice.

The base quota for the General category is 555.7 mt. See § 635.27(a). Each of the General category time periods (January, June through August, September, October through November, and December) is allocated a subquota or portion of the annual General category quota. Although it is called the ''January'' subquota, the regulations allow the General category fishery under this quota to continue until the subquota is reached or March 31, whichever comes first. The baseline subquotas for each time period are as follows: 29.5 mt for January; 277.9 mt for June through August; 147.3 mt for September; 72.2 mt for October through November; and 28.9 mt for December. Any unused General category quota rolls forward from one time period to the next and is available for use in subsequent time periods within the fishing year. Effective January 1, 2019, NMFS transferred 19.5 mt of the 28.9-mt General category quota allocated for the December 2019 period to the January 2019 period, resulting in an adjusted subquota of 49 mt for the January period and a subquota of 9.4 mt for the December 2019 period (83 FR 67140, December 28, 2018). Effective February 8, 2019, NMFS transferred 26 mt from the Reserve category to the General category January 2019 subquota period, resulting in an adjusted subquota of 75 mt for the January period and 3.5 mt for the Reserve category (84 FR 3724, February 13, 2019). Effective February 25, 2019, NMFS transferred an additional 25 mt from the Reserve category to the General category, in the same notice as NMFS made the annual reallocation of Purse Seine category quota to the Reserve category, resulting in an adjusted subquota of 100 mt for the General category 2019 January subquota period and 143 mt for the Reserve category (FR document 2019–03554 filed for public inspection, February 25, 2019).

Based on the best available landings information for the General category BFT fishery, NMFS has determined that the adjusted General category January 2019 subquota of 100 mt has been reached (*i.e.,* as of February 27, reported landings total approximately 97 mt) and that the General category fishery should be closed. Therefore, retaining, possessing, or landing large medium or giant BFT by persons aboard vessels permitted in the Atlantic tunas General category and the HMS Charter/Headboat category (while fishing commercially) must cease at 11:30 p.m. local time on February 28, 2019. The General category will reopen automatically on June 1, 2019, for the June through August 2019. This action applies to Atlantic tunas General category (commercial) permitted vessels and HMS Charter/Headboat category permitted vessels with a commercial sale endorsement when fishing commercially for BFT and is taken consistent with the regulations at § 635.28(a)(1). The intent of this closure is to prevent overharvest of the available January subquota.

Fishermen may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the ''Careful Catch and Release'' brochure available at *https://www.fisheries.noaa.gov/resource/outreach-and-education/careful-catch-and-release-brochure/*.

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely. Dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustment, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, General and HMS Charter/Headboat category vessel owners are required to report the catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *hmspermits.noaa.gov,* using the HMS Catch Reporting app, or calling (888) 872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m.).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments are necessary to ensure available subquotas are not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information

Line at (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. These fisheries are currently underway and delaying this action would be contrary to the public interest as it could result in BFT landings further exceeding the January subquota, which could result in the need to reduce quota for the General category later in the year and thus could affect later fishing opportunities. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under § 635.28(a)(1) (BFT fishery closures), and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: February 27, 2019.

Karen H. Abrams,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2019–03816 Filed 2–27–19; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170816769–8162–02]

RIN 0648–XG845

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Greater Than or Equal to 50 Feet Length Overall Using Hook-and-Line Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels greater than or equal to 50 feet length overall (LOA) using hook-and-line gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2019 Pacific cod total allowable catch apportioned to catcher vessels greater than or equal to 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), February 27, 2019, through 1200 hours, A.l.t., June 10, 2019.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679. Regulations governing sideboard protections for GOA groundfish fisheries appear at subpart B of 50 CFR part 680.

The A season allowance of the 2019 Pacific cod total allowable catch (TAC) apportioned to catcher vessels greater than or equal to 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA is 319 metric tons (mt), as established by the final 2018 and 2019 harvest specifications for groundfish of the GOA (83 FR 8768, March 1, 2018).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the A season allowance of the 2019 Pacific cod TAC apportioned to catcher vessels greater than or equal to 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 259 mt and is setting aside the remaining 60 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels greater than or equal to 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA. While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of Pacific cod by catcher vessels greater than or equal to 50 feet LOA using hook-and-line gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of February 26, 2019.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 27, 2019.

Karen H. Abrams,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2019–03813 Filed 2–27–19; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 42
Monday, March 4, 2019

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2018–0041]

RIN 0579–AE48

Amendments to the Pale Cyst Nematode Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the domestic quarantine regulations for pale cyst nematode by adding procedures that would allow persons to review and comment on the protocols for regulating and deregulating quarantine and associated areas. As part of this proposal, we are making the protocols publicly available. We are proposing these actions in response to a court order requiring the Animal and Plant Health Inspection Service to facilitate public input into the development of protocols for deregulating fields for pale cyst nematode. The changes we propose would make the protocols more accessible and give persons the opportunity to comment on their development.

DATES: We will consider all comments that we receive on or before May 3, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0041*.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2018–0041, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0041* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Evelia Sosa, Assistant Director, Pest Management, PHP, PPQ, APHIS, 4700 River Road, Unit 137, Riverdale, MD 20737; (301) 851–2217; *Evelia.Sosa@aphis.usda.gov*.

SUPPLEMENTARY INFORMATION:

Background

The pale cyst nematode (PCN, *Globodera pallida*) is a major pest of potato crops in cool-temperature areas. Other hosts of this pest include tomatoes, eggplants, peppers, tomatillos, and some weeds. The PCN is thought to have originated in Peru and is now widely distributed in many potato-growing regions of the world. Females commonly form cysts containing 200 to 600 eggs, which can remain dormant and viable in soil for up to 30 years. Affected potato plants may exhibit yellowing, wilting, or death of foliage. Unmanaged infestations can cause potato yield losses ranging from 20 to 70 percent. The spread of PCN in the United States could result in a significant loss of domestic and foreign markets for U.S. potatoes and other host commodities.

Section 414 of the Plant Protection Act (PPA, 7 U.S.C. 7714) provides that the Secretary of Agriculture may, under certain conditions, hold, seize, quarantine, treat, apply other remedial measures to destroy or otherwise dispose of any plant, plant pest, plant product, article, or means of conveyance that is moving, or has moved into or through the United States or interstate if the Secretary has reason to believe the article is a plant pest or is infested with a plant pest at the time of movement.

The PCN regulations in 7 CFR part 301 (Subpart—Pale Cyst Nematode, §§ 301.86 through 301.86–9, referred to below as the regulations) set out quarantine and movement restrictions for regulated articles from fields infested with PCN and associated fields.

Section 301.86–3 sets out procedures for determining the areas quarantined for PCN. Paragraph (a) of § 301.86–3 states that, in accordance with the criteria listed in § 301.86–3(c), the Administrator of the Animal and Plant Health Inspection Service (APHIS) will designate as a quarantined area each field that has been found to be infested with PCN, each field that has been found to be associated with an infested field, and any area that the Administrator considers necessary to quarantine because of its inseparability for quarantine enforcement purposes from infested or associated fields.

Under § 301.86–3(c), APHIS designates a field as being infested if PCN is found in that field. A field is designated as an associated field, meaning that the field is at risk for PCN, if it meets certain criteria. These include any field in which PCN host crops were grown in the last 10 years, *and* (1) The field shares a border with an infested field; or (2) the field came into contact with a regulated article listed in § 301.86–2 from an infested field within the last 10 years; or (3) within the last 10 years, the field shared ownership, tenancy, seed, drainage or runoff, farm machinery, or other shared cultural practices with an infested field that could allow spread of PCN.

Paragraph (d) of § 301.86–3 states that an infested field will be removed from quarantine when a protocol approved by the Administrator as sufficient to support removal of infested fields from quarantine has been completed and the field has been found to be free from PCN based on the protocol. The removal from quarantine of any associated fields also requires steps under an approved protocol.

The PCN regulations were first established in an interim rule published September 12, 2007 (72 FR 51975–51988, Docket No. APHIS–2006–0143), after parts of Bingham and Bonneville Counties, ID, were quarantined upon discovery of PCN in several potato fields in 2006. The interim rule restricted the interstate movement of potatoes and other regulated articles from the quarantined area to prevent the spread of PCN to non-infested areas of the United States. We included in § 301.86–3 of the interim rule the provision that an infested field will be removed from quarantine when a 3-year biosurvey protocol approved by APHIS has been

completed and the field has been found to be free of PCN. The 3-year biosurvey protocol involves planting PCN host crops in soil from a field and sampling the soil for PCN. This process must be repeated over three crop cycles with negative results in order for APHIS to deregulate a field for PCN.

On April 29, 2009 (74 FR 19374–19382, Docket No. APHIS–2006–0143), we published a final rule based on our evaluation of public comments that we received on the interim rule and input from an independent science panel. Based on our review of this information, we determined that including the 3-year biosurvey protocol in the regulations as the only approach for deregulating fields precluded the potential use of other methods that would be sufficient for evaluating fields for PCN, so we broadened the approach in § 301.86–3(d)(1) to read ''a protocol approved by the Administrator as sufficient to support removal of infested fields from quarantine.'' We stated in the final rule that we would continue to solicit stakeholder input as we develop the field removal protocol and update affected producers and other interested parties on our progress.

On April 28, 2015, a group of Idaho potato farmers subject to the PCN quarantine filed a complaint against APHIS in the U.S. District Court in Idaho. Among the allegations in the complaint was that APHIS violated provisions of the PPA and the Administrative Procedure Act (APA) by not developing accessible regulations and failing to follow notice and comment requirements of the APA. The plaintiffs alleged that the final rule contemplated further rulemaking through the creation of protocols to be used to support removal of infested and associated fields from regulation. Because APHIS had not publically issued the protocol referenced in the final rule, the plaintiffs stated they were unclear as to what methods and data APHIS drew on in deciding whether to deregulate infested and associated fields, making the requirements imposed on the plaintiffs vague and impossible to satisfy. The complaint asked the court to set aside the final rule and end the quarantine and regulation of all fields owned and farmed by the plaintiffs.

In a decision filed March 20, 2018,[1] the court declined to set aside the final rule, citing the economic value of the potato industry and noting that ending regulation for PCN would have adverse consequences on the State of Idaho and the United States. However, the court ruled that APHIS did not satisfy the requirements of the APA because the deregulation protocols ''change existing law by adding new substantive requirements for the quarantining and deregulating of PCN infested and associated fields to be implemented by APHIS pursuant to its authority under the PPA.'' Accordingly, the protocols were determined to be legislative rules for which APHIS is required to provide a notice of availability of the protocols in the **Federal Register**, provide a period for interested individuals to comment on the protocols, and publish the adopted protocols not less than 30 days before the effective date. The court ordered APHIS to immediately begin the process of providing for public notice and comment on the protocols and to satisfy the APA notice and comment requirements for all current and future actions relating to regulation of PCN.

We are responding to the court order in this rulemaking by proposing to include procedures in the regulations for public notice and comment of the PCN deregulation protocols. Although not ordered to do so by the court, we are proposing to do the same for the criteria APHIS uses to make initial designations of fields. We are proposing to amend § 301.86–3, paragraphs (c) and (d), to provide that any substantive changes to the protocols will first be announced in a **Federal Register** notice that informs the public of the proposed change and solicits comment. After we review and consider public comments on the changes, we would publish another notice in the **Federal Register** informing the public of any changes we made to the protocols.

The protocols are available for comment on the *Regulations.gov* website and in our reading room (see **ADDRESSES** above for instructions for accessing *Regulations.gov* and information on the location and hours of the reading room). We would make future versions of protocols available on the APHIS website or upon request from any local office of APHIS-Plant Protection and Quarantine; local offices are listed in telephone directories.

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. This proposed rule is not expected to be an Executive Order 13771 regulatory action because this proposed rule is not significant under Executive Order 12866.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the *Regulations.gov* website (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

According to the Small Business Administration, entities whose main activity is potato farming (classified under NAICS 111211) are considered small if they have $750,000 or less in annual receipts. Based on the 2012 Census of Agriculture, there were about 24,000 farms in Idaho, of which around 800 were considered to be primarily potato farms. Bingham and Bonneville Counties had 122 and 36 potato farms, respectively. There were about 2,000 farms in Idaho with farm sales greater than $500,000, of which around 1,200 farms had farm sales greater than $1 million. According to the 2012 Census, 142 of Bingham County's 1,265 farm operations (about 11 percent) had farm sales greater than $500,000, while in Bonneville County, 56 of the 893 farm operations (about 6 percent) had farm sales greater than $500,000. Although the distribution of potato farms with farm sales above $500,000 (or $750,000) is not known, it is reasonable to conclude that many of the potato farms in Bingham and Bonneville counties are under the threshold and would be considered as small business entities.

However, the proposed rule would not impose new or additional burdens on small entities as this is an administrative action for which there would be no additional costs.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with

[1] *https://www.gpo.gov/fdsys/pkg/USCOURTS-idd-1_15-cv-00143/pdf/USCOURTS-idd-1_15-cv-00143-2.pdf.*

this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no reporting, recordkeeping, or third party disclosure requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we propose to amend 7 CFR part 301 as follows:

Subpart S—Pale Cyst Nematode

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 issued under Sec. 204, Title II, Public Law 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Public Law 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. Section 301.86–3 is amended as follows:

■ a. In paragraph (a), by removing the words ''*http://www.aphis.usda.gov/plant_health/plant_pest_info/potato/pcn.shtml*'' and adding the words ''*https://www.aphis.usda.gov/planthealth/pcn*'' in their place; and

■ b. By revising paragraphs (c)(1) and (d).

The revisions read as follows:

§ 301.86–3 Quarantined areas.

* * * * *

(c) * * *

(1) *Infested fields.* A field will be designated as an infested field for pale cyst nematode upon a determination that viable pale cyst nematode is present in the field. The determination will be made in accordance with the criteria established by the Administrator for the designation of infested fields. The criteria are presented in a protocol document that may be viewed at *https://www.aphis.usda.gov/planthealth/pcn.* The protocol may also be obtained by request from any local office of Plant Protection and Quarantine; local offices are listed in telephone directories. Any substantive changes we propose to make to the protocol will be published for comment in the **Federal Register**. After we review the comments received, we will publish another notice in the **Federal Register** informing the public of any changes to the protocol.

* * * * *

(d) *Removal of fields from quarantine—(1) Infested fields.* An infested field will be removed from quarantine for pale cyst nematode upon a determination that no viable pale cyst nematode is detected in the field. The determination will be made in accordance with criteria established by the Administrator and sufficient to support removal of infested fields from quarantine. The criteria are presented in a protocol document as provided in (d)(4) of this section along with information for viewing the protocol.

(2) *Associated fields.* An associated field will be removed from quarantine for pale cyst nematode once surveys are completed and pale cyst nematode is not detected in the field. The determination will be made in accordance with criteria established by the Administrator and sufficient to support removal of associated fields from quarantine. The criteria are presented in a protocol document as provided in (d)(4) of this section along with information for viewing the protocol.

(3) *Removal of other areas from quarantine.* If the Administrator has quarantined any area other than infested or associated fields because of its inseparability for quarantine enforcement purposes from infested or associated fields, as provided in paragraph (a) of this section, that area will be removed from quarantine when the relevant infested or associated fields are removed from quarantine.

(4) *Protocol for removal of fields from quarantine.* The Administrator will remove infested and associated fields, and other areas as provided in this section, from quarantine for pale cyst nematode in accordance with the protocols published on the Plant Protection and Quarantine website at *https://www.aphis.usda.gov/planthealth/pcn.* The protocols may also be obtained by request from any local office of Plant Protection and Quarantine; local offices are listed in telephone directories. Any substantive changes we propose to make to the protocols will be published for comment in the **Federal Register**. After we review the comments received, we will publish another notice in the **Federal Register** informing the public of any changes to the protocols.

Done in Washington, DC, this 25th day of February 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–03673 Filed 3–1–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0033; Airspace Docket No. 19–AGL–3]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Dickinson, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E surface airspace and Class E airspace areas extending upward from 700 feet or more above the surface of the earth at Dickinson-Theodore Roosevelt Regional Airport (formerly Dickinson Municipal Airport) in Dickinson, ND. The FAA is proposing this action as the result of an airspace review caused by the decommissioning of the Dickinson non-directional radio beacon (NDB). The geographic coordinates for the airport in the associated airspace and the airport name would be updated to coincide with the FAA's aeronautical database. Also, the Dickinson VHF omni-directional radio range and tactical air navigational aid (VORTAC) is no longer needed in the description of the E–5 airspace and will be removed. Airspace redesign is necessary for the safety and management of instrument flight rules (IFR) operations at these airports.

DATES: Comments must be received on or before April 18, 2019.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2019–0033; Airspace Docket No. 19–AGL–3, at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between

9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Witucki, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5900.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace at Dickinson-Theodore Roosevelt Regional Airport, in support of standard instrument approach procedures for IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2019–0033; Airspace Docket No. 19–AGL–3.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air-traffic/publications/airspace-amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending Class E surface airspace to within a 4.1-mile radius (reduced from 4.4 miles) of Dickinson-Theodore Roosevelt Regional Airport, Dickinson, ND and removing the extension to the southeast associated with the Dickinson non-directional radio beacon. Also, propose amending Class E airspace extending upward from 700 feet above the surface within a 6.6-mile radius (reduced from 8.3 miles) of the Dickinson-Theodore Roosevelt Regional Airport and removing the extension to the southeast associated with the Dickinson non-directional radio beacon. This action would enhance safety and the management of IFR operations at the airport. Also, the airport name and geographic coordinates would be adjusted to coincide with the FAA's aeronautical database. The Dickenson VORTAC is no longer needed to describe the airspace and will be removed.

Class E airspace designations are published in paragraphs 6002 and 6005 of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas

AGL ND E2 Dickinson, ND [Amended]

Dickinson-Theodore Roosevelt Regional Airport, ND
(Lat. 46°47′50″ N, long. 102°48′07″ W)

Within a 4.1-mile radius of the Dickinson-Theodore Roosevelt Regional Airport.

* * * * *

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

AGL ND E5 Dickinson, ND [Amended]

Dickinson-Theodore Roosevelt Regional Airport, ND
(Lat. 46°47′50″ N, long 102°48′07″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Dickinson-Theodore Roosevelt Regional Airport.

Issued in Fort Worth, Texas, on February 25, 2019.

John Witucki,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2019–03727 Filed 3–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2019–0060; Airspace Docket No. 18–ASO–20]

RIN 2120–AA66

Proposed Removal of Area Navigation (RNAV) Route Q–106; Southern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove RNAV route Q–106 which currently extends between the SMELZ, FL, waypoint (WP) and the GADAY, AL, WP. With the implementation additional Q routes by the Florida Metroplex Q-route Project, the FAA has determined that Q–106 is no longer required.

DATES: Comments must be received on or before April 18, 2019.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2019–0060; Airspace Docket No. 18–ASO–20 at the beginning of your comments. You may also submit comments through the internet at *http://www.regulations.gov.*

FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington DC, 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741–6030, or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2019–0060; Airspace Docket No. 18–ASO–20) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2019–0060; Airspace Docket No. 18–ASO–20.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the

comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to remove RNAV route Q–106. Q–106 extends between the SMELZ, FL, WP (northwest of the Lakeland, FL, VORTAC) and the GADAY, AL, WP (northeast of the Crestview, FL, VORTAC). The implementation of the Florida Metroplex Q-route Project (83 FR 43750; August 28, 2018), that became effective on November 8, 2018, increased the number of RNAV Q-routes that extend through the area served by Q–106. As a result, the FAA determined that Q–106 is obsolete and no longer required.

Q-routes are published in paragraph 2006 of FAA Order 7400.11C dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Q-route listed in this document would be subsequently removed from the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 2006—United States Area Navigation Routes Q–106 [Remove]

Issued in Washington, DC, on February 27, 2019.

Rodger A. Dean Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2019–03839 Filed 3–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 33

[Docket No. RM19–4–000]

Mergers or Consolidations by a Public Utility; Correction

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: This document contains corrections to the **Federal Register** title for the notice of proposed rulemaking (NOPR) in Docket No. RM19–4–000 that was published in the **Federal Register** on Thursday, November 29, 2018. This correction clarifies the differences in the titles of the NOPR and the Final Rule that published on February 26, 2019.

DATES: Effective March 4, 2019.

FOR FURTHER INFORMATION CONTACT:

Eric Olesh (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6524

Regine Baus (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8757.

SUPPLEMENTARY INFORMATION:

Need for Correction

On November 15, 2018, the Commission issued a ''Notice of Proposed Rulemaking'' (NOPR), in the above-captioned proceeding. This NOPR published in the **Federal Register** with the heading titled: *Implementation of Amended Section 203(a)(1)(B) of the Federal Power Act.*[1]

On February 21, 2019, the Commission issued a ''Final Rule'' in the above-captioned proceeding titled: *Implementation of Amended Section 203(a)(1)(B) of the Federal Power Act.*

[1] Implementation of Amended Section 203(a)(1)(B) of the Federal Power Act, (83 FR 61338).

The title of the Final Rule was flagged by the **Federal Register**. The **Federal Register** directed that the title be revised. Accordingly, per the **Federal Register**'s direction, the title of the Final Rule was subsequently changed to ''*Mergers or Consolidations by a Public Utility.*'' [2] This document serves to correct the **Federal Register** published title of the NOPR to coincide with the Final Rule published on February 26, 2019.

Federal Register Correction

1. Correct the **Federal Register** title of the NOPR, in the above-captioned proceeding, Implementation of Amended Section 203(a)(1)(B) of the Federal Power Act, to read as follows:

Mergers or Consolidations by a Public Utility

Dated: February 26, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03686 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

[2] Mergers or Consolidations by a Public Utility, (84 FR 6069).

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2019–0083]

RIN 1625–AA08

Special Local Regulation; Bush River and Otter Point Creek, Harford County, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish special local regulations for certain waters of the Bush River and Otter Point Creek. This action is necessary to provide for the safety of life on these navigable waters located at Edgewood, Harford County, MD, during a high-speed power boat racing event on May 11, 2019, and May 12, 2019. This proposed rulemaking would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port Maryland-National Capital Region or Coast Guard Patrol Commander. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before April 3, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2019–0083 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Mr. Ron Houck, U.S. Coast Guard Sector Maryland-National Capital Region; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
PATCOM Coast Guard Patrol Commander
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Carolina-Virginia Racing Association of Havre de Grace, MD has notified the Coast Guard that it will be conducting the Flying Point Park Outboard Regatta from 10 a.m. to 6 p.m. on May 11, 2019, and from 10 a.m. to 6 p.m. on May 12, 2019. The high-speed power boat racing event consists of approximately 60 participating outboard hydroplane and runabout race boats of various classes, 9 to 14 feet in length, with 4 to 12 boats racing in 3-lap heats, along a designated, marked racetrack-type course located in Bush River and Otter Point Creek at Edgewood, Harford County, MD. Hazards from the power boat racing event include participants operating within and adjacent to designated navigation channels and interfering with vessels intending to operate within those channels, as well as operating within approaches to local public boat ramps, private marinas and yacht clubs, and waterfront businesses. The Captain of the Port (COTP) Maryland-National Capital Region has determined that potential hazards associated with the power boat racing event would be a safety concern for anyone intending to operate within certain waters of Bush River and Otter Point Creek in Harford County, MD, operating in or near the event area.

The purpose of this rulemaking is to protect event participants, spectators and transiting vessels on certain waters of Bush River and Otter Point Creek before, during, and after the scheduled event. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1233, which authorizes the Coast Guard to establish and define special local regulations.

III. Discussion of Proposed Rule

The COTP Maryland-National Capital Region proposes to establish special local regulations to be enforced from 9:30 a.m. to 6:30 p.m. on May 11, 2019, and from 9:30 a.m. to 6:30 on May 12, 2019. The regulated area would cover all navigable waters of the Bush River and Otter Point Creek, from shoreline to shoreline, bounded to the north by a line drawn from the western shoreline of the Bush River at latitude 39°27′15″ N, longitude 076°14′39″ W and thence eastward to the eastern shoreline of the Bush River at latitude 39°27′03″ N, longitude 076°13′57″ W; and bounded to the south by the Amtrak Railroad Bridge, across the Bush River at mile 6.8, between Perryman, MD, and Edgewood, MD.

This proposed rule provides additional information about areas within the regulated area, their definitions, and the restrictions that would apply. These areas include a ''Race Area'', ''Buffer Zone'' and ''Spectator Area''.

The proposed duration of the special local regulations and size of the regulated area are intended to ensure the safety of life on these navigable waters before, during, and after the high-speed power boat races, scheduled from 10 a.m. until 6 p.m. on May 11, 2019, and May 12, 2019. The COTP and PATCOM would have authority to forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area would be required to immediately comply with the directions given by the COTP or Coast Guard Patrol Commander (PATCOM). If a person or vessel fails to follow such directions, the Coast Guard may expel them from the area, issue them a citation for failure to comply, or both. Official Patrols are any vessel assigned or approved by the Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

Except for Flying Point Park Outboard Regatta participants and vessels already at berth, a vessel or person would be required to get permission from the COTP or PATCOM before entering the regulated area. Vessel operators can request permission to enter and transit through the regulated area by contacting

the PATCOM on VHF–FM channel 16. Vessel traffic would be able to safely transit the regulated area once the PATCOM deems it safe to do so.

If permission is granted by the COTP or PATCOM, a person or vessel would be allowed to enter the regulated area or pass directly through the regulated area as instructed. Vessels would be required to operate at a safe speed that minimizes wake while within the regulated area. Official patrol vessels will direct spectator vessels while within the regulated area. Vessels would be prohibited from loitering within the navigable channel. Only participant vessels and official patrol vessels would be allowed to enter the race area. A person or vessel not registered with the event sponsor as a participant or assigned as official patrols would be considered a spectator. Spectators are only allowed inside the regulated area if they remain within the designated spectator area. All spectator vessels must be anchored or operate at a No Wake Speed within the designated spectator area. Official patrol vessels will direct spectator vessels to the spectator area. Spectators must contact the Coast Guard Patrol Commander to request permission to pass through the regulated area. If permission is granted, spectators must pass directly through the regulated area at safe speed and without loitering.

The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, duration and time of year of the regulated area, which would impact a small designated area of the Bush River and Otter Point Creek for 18 total enforcement hours. The Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the status of the regulated area. Moreover, the rule would allow vessels to seek permission to enter the regulated area, and vessel traffic would be able to safely transit the regulated area once the PATCOM deems it safe to do so.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves implementation of regulations within 33 CFR part 100 applicable to organized marine events on the navigable waters of the United States that could negatively impact the safety

of waterway users and shore side activities in the event area lasting for 18 hours. Normally such actions are categorically excluded from further review under paragraph L[61] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *http://www.regulations.gov/privacyNotice.*

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 33 CFR 1.05–1.

■ 2. Add § 100.501T05–0083 to read as follows:

§ 100.501T05–0083 Special Local Regulation; Bush River and Otter Point Creek, Harford County, MD.

(a) *Definitions.* As used in this section:

Buffer Zone is a neutral area that surrounds the perimeter of the Race Area within the regulated area described by this section. The purpose of a buffer zone is to minimize potential collision conflicts with marine event participants or race boats and spectator vessels or nearby transiting vessels. This area provides separation between a Race Area and a specified Spectator Area or other vessels that are operating in the vicinity of the regulated area established by the special local regulations.

Captain of the Port (COTP) Maryland-National Capital Region means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region or any Coast Guard commissioned, warrant or petty officer who has been authorized by the COTP to act on his behalf.

Coast Guard Patrol Commander (PATCOM) means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated by the Commander, Coast Guard Sector Maryland-National Capital Region.

Official Patrol means any vessel assigned or approved by Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

Participant means a person or vessel registered with the event sponsor as participating in the Flying Point Park Outboard Regatta or otherwise designated by the event sponsor as having a function tied to the event.

Race Area is an area described by a line bound by coordinates provided in latitude and longitude that outlines the boundary of a race area within the regulated area defined by this section.

Spectator means a person or vessel not registered with the event sponsor as participants or assigned as official patrols.

Spectator Area is an area described by a line bound by coordinates provided in latitude and longitude that outlines the boundary of a spectator area within the regulated area defined by this part.

(b) *Locations.* All coordinates reference Datum NAD 1983.

(1) *Regulated area.* All navigable waters of Bush River and Otter Point Creek, from shoreline to shoreline, bounded to the north by a line drawn from the western shoreline of the Bush River at latitude 39°27′15″ N, longitude 076°14′39″ W and thence eastward to the eastern shoreline of the Bush River at latitude 39°27′03″ N, longitude 076°13′57″ W; and bounded to the south by the Amtrak Railroad Bridge, across the Bush River at mile 6.8, between Perryman, MD and Edgewood, MD. The following locations are within the regulated area:

(2) *Race Area.* The race area is a polygon in shape measuring approximately 540 yards in length by 270 yards in width. The area is bounded by a line commencing at position latitude 39°26′33.1″ N, longitude 076°15′46.8″ W; thence westerly to latitude 39°26′33.1″ N, longitude 076°15′49.3″ W; thence northerly to latitude 39°26′37.1″ N, longitude 076°15′52.4″ W; thence northeasterly to latitude 39°26′40.0″ N, longitude 076°15′52.5″ W; thence easterly to latitude 39°26′45.9″ N, longitude 076°15′32.2″ W; thence southeasterly to latitude 39°26′45.3″ N, longitude 076°15′30.0″ W; thence southerly to latitude 39°26′43.8″ N, longitude 076°15′29.1″ W; thence southerly to latitude 39°26′42.2″ N, longitude 076°15′28.9″ W; thence southwesterly to latitude 39°26′40.8″ N, longitude 076°15′29.3″ W; thence westerly terminating at point of origin.

(3) *Buffer Zone.* The buffer zone surrounds the entire race area described in the preceding paragraph of this section. This area is a polygon in shape and provides a buffer around the perimeter of the race area. The area is bounded by a line commencing at the shoreline at Flying Point Park at position latitude 39°26′31.9″ N, longitude 076°15′32.5″ W; thence westerly to latitude 39°26′30.5″ N, longitude 076°15′52.7″ W; thence northerly to latitude 39°26′39.9″ N, longitude 076°16′00.0″ W; thence easterly to latitude 39°26′51.6″ N, longitude 076°15′26.7″ W; thence southerly to latitude 39°26′37.0″ N, longitude 076°15′22.5″ W; thence southerly to latitude 39°26′33.7″ N, longitude 076°15′22.8″ W, located at the shoreline at Flying Point Park.

(4) *Spectator Area.* The designated spectator area is a polygon in shape and is bounded by a line commencing at position latitude 39°26′39.9″ N, longitude 076°15′23.3″ W; thence east to

latitude 39°26′39.6'' N, longitude 076°15′19.4″ W; thence south to latitude 39°26′36.6″ N, longitude 076°15′18.7″ W; thence west to latitude 39°26′37.0″ N, longitude 076°15′22.5″ W; thence north to point of origin.

(c) *Special local regulations:* (1) The COTP Maryland-National Capital Region or PATCOM may forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area must immediately comply with the directions given by the patrol. Failure to do so may result in the Coast Guard expelling the person or vessel from the area, issuing a citation for failure to comply, or both. The COTP Maryland-National Capital Region or PATCOM may terminate the event, or a participant's operations at any time the COTP Maryland-National Capital Region or PATCOM believes it necessary to do so for the protection of life or property.

(2) Except for participants and vessels already at berth, a person or vessel within the regulated area at the start of enforcement of this section must immediately depart the regulated area.

(3) A spectator must contact the PATCOM to request permission to either enter or pass through the regulated area. The PATCOM, and official patrol vessels enforcing this regulated area, can be contacted on marine band radio VHF–FM channel 16 (156.8 MHz) and channel 22A (157.1 MHz). If permission is granted, the spectator may enter the designated Spectator Area or must pass directly through the regulated area as instructed by PATCOM. A vessel within the regulated area must operate at safe speed that minimizes wake. A spectator vessel must not loiter within the navigable channel while within the regulated area.

(4) A person or vessel that desires to transit, moor, or anchor within the regulated area must first obtain authorization from the COTP Maryland-National Capital Region or PATCOM. A person or vessel seeking such permission can contact the COTP Maryland-National Capital Region at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz) or the PATCOM on Marine Band Radio, VHF–FM channel 16 (156.8 MHz).

(5) Only participant vessels and official patrol vessels are allowed to enter the race area.

(6) Spectators are only allowed inside the regulated area if they remain within the designated spectator area. All spectator vessels must be anchored or operate at a No Wake Speed within the designated spectator area. Official patrol vessels will direct spectator vessels to the spectator area. Spectators must contact the Coast Guard Patrol Commander to request permission to pass through the regulated area. If permission is granted, spectators must pass directly through the regulated area at safe speed and without loitering.

(7) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue a marine information broadcast on VHF–FM marine band radio announcing specific event date and times.

(d) *Enforcement officials.* The Coast Guard may be assisted with marine event patrol and enforcement of the regulated area by other Federal, State, and local agencies.

(e) *Enforcement periods.* This section will be enforced from 9:30 a.m. to 6:30 p.m. on May 11, 2019, and, from 9:30 a.m. to 6:30 p.m. on May 12, 2019.

Dated: February 26, 2019.

Joseph B. Loring,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2019–03781 Filed 3–1–19; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2018–0609; FRL–9990–30–Region 4]

Air Plan Approval; Kentucky: Jefferson County Process Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve changes to the Jefferson County portion of the Kentucky State Implementation Plan (SIP), submitted by the Commonwealth of Kentucky, through the Energy and Environment Cabinet (Cabinet), through a letter dated March 15, 2018. The proposed SIP revision was submitted by the Cabinet on behalf of the Louisville Metro Air Pollution Control District (District) and makes minor ministerial amendments to regulations regarding new and existing process operations.

DATES: Comments must be received on or before April 3, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2018–0609 at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Andres Febres, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8966. Mr. Febres can also be reached via electronic mail at *febres-martinez.andres@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What action is EPA proposing?

EPA is proposing to approve changes to the Jefferson County portion of the Kentucky SIP that were provided to EPA through a letter dated March 15, 2018.[1] EPA is proposing to approve the portions of this SIP revision that make changes to the District's Regulation 6.09—*Standards of Performance for Existing Process Operations,* and Regulation 7.08—*Standards of Performance for New Process Operations.*[2] The March 15, 2018, SIP revision makes minor and ministerial changes that do not alter the meaning of these regulations but rather are intended to clarify the applicability of these regulations, as well as reduce redundancy in the particulate matter (PM) and opacity standards. The SIP revision updates the current SIP-approved versions of Regulation 6.09

[1] EPA notes that the Agency received the SIP revision on March 23, 2018.

[2] EPA also notes that the Agency received several other revisions to the Jefferson County portion of the Kentucky SIP submitted with the same March 15, 2018, cover letter. EPA will be considering action on the remaining revisions in separate actions.

(version 6) and Regulation 7.08 (version 3) to versions 7 and version 4, respectively. The changes that are being proposed for approval in this rulemaking and EPA's rationale for proposing approval are described in more detail below.

II. EPA's Analysis of the State Submittal

As mentioned in Section I of this document, the portion of Jefferson County's March 15, 2018, SIP revision that EPA is proposing to approve makes changes to two Jefferson County Air Quality Regulations. Specifically, the SIP revision updates the SIP-approved version of Regulation 6.09 to version 7, and the SIP-approved version of Regulation 7.08 to version 4.

(1) Regulation 6.09, Standards of Performance for Existing Process Operations

Jefferson County's Regulation 6.09 provides for the control of emissions from existing process operations and includes standards for PM emissions, as well as nitrogen oxides (NO_X) emissions. Jefferson County's March 15, 2018, SIP revision requests that EPA incorporate version 7 of Regulation 6.09 into the SIP. Version 7 amends two sections of Regulation 6.09: Section 1, *Applicability,* in order to clarify the applicability of this regulation through slightly modified language; and Section 3, *Standards for Particulate Matter,* in order to eliminate redundancies within that section.

Section 1.1 of the current SIP-approved version of Regulation 6.09 states that the provisions of this regulation apply to process operations that were either in existence or had an approved construction permit on or before September 1, 1976. With the amendments in version 7, Jefferson County makes minor edits to clarify that the provisions of this regulation apply to process operations that not only were in existence on or before September 1, 1976, but also to those process operations that had either commenced construction, reconstruction, or a modification by that date. In addition, Jefferson County rewords, for clarification purposes, the part of Section 1.1 that specifies that Regulation 6.09 applies to those process operations not otherwise covered under any other portion of Regulation 6, but the scope, meaning, and applicability of Regulation 6.09 remain the same.

Section 3 of the current SIP-approved version of Regulation 6.09 includes specific standards for PM emissions from existing process operations. With the amendments in version 7, Jefferson County deletes Sections 3.3 and 3.4 of Regulation 6.09. Section 3.3 contains an opacity standard for PM that limits process operation emissions to 20 percent opacity; and Section 3.4 contains a Mass emission standard for PM that limits process operation emissions to emissions rates provided in Table 1 of Regulation 6.09. Both standards for PM emissions are unnecessary because they are already established under sections 3.1 and 3.2 of Regulation 6.09. By deleting Sections 3.3 and 3.4, Jefferson County is not removing any emissions limit for existing process operations, but is simply removing redundancy in the current SIP-approved version of the regulation.

The March 15, 2018, SIP revision does not change the scope or meaning of Regulation 6.09, nor does it modify how the regulation works. These changes are minor and ministerial in nature and help to clean up and clarify the regulation of existing process operations. EPA has made the preliminary determination that the aforementioned changes will not have a negative impact on air quality in the area and is therefore proposing to approve version 7 of Regulation 6.09 into the Jefferson County portion of the Kentucky SIP.

(2) Regulation 7.08, Standards of Performance for New Process Operations

Like Jefferson County's Regulation 6.09, Regulation 7.08 provides for the control of emissions from process operations, but these provisions apply to new process operations rather than existing ones. Jefferson County's March 15, 2018, SIP revision requests that EPA adopt version 4 of Regulation 7.08 into the SIP. Version 4 of Regulation 7.08 makes changes similar to those in version 7 of Regulation 6.09 by amending the two corresponding sections: Section 1, *Applicability,* in order to clarify the applicability of this regulation through slightly modified language; and Section 3, *Standards for Particulate Matter,* in order to eliminate redundancies within that section.

Section 1 of the current SIP-approved version of Regulation 7.08 states that the provisions of this regulation apply to process operations that commenced construction after September 1, 1976. With the amendments in version 4, Jefferson County clarifies that the provisions of this regulation apply to process operations that not only had commenced construction after September 1, 1976, but also to those that had either commenced modification or reconstruction after this date. As with the changes in Regulation 6.09, Jefferson County also rewords, for clarification purposes, the provision in Section 1 that specifies that this regulation applies to those process operations not otherwise covered under any other portion of Regulation 7, but the scope, meaning, and applicability remain the same.

Section 3 of the current SIP-approved version of Regulation 7.08 includes specific standards for PM emissions of new process operations. With the amendments in version 4, Jefferson County deletes Section 3.2, which contains the 20 percent opacity limit for PM from process operation emissions. This opacity standard is unnecessary because it is already established in section 3.1.1 of Regulation 7.08. By deleting Section 3.2, Jefferson County is not removing any emissions limitation for new process operations, but is simply removing a redundancy that exists in the current SIP-approved version of the regulation.

Just as with Regulation 6.09 above, the March 15, 2018, SIP revision does not change the meaning or scope of Regulation 7.08, nor does it modify how the regulation works. These changes are minor and ministerial in nature and help to clean up and clarify the regulation of new process operations. EPA has made the preliminary determination that the aforementioned changes will not have a negative impact on air quality in the area and is therefore proposing to approve version 4 of Regulation 7.08 into the Jefferson County portion of the Kentucky SIP.

III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Jefferson County's Regulation 6.09, *Standards of Performance for Existing Process Operations,* Version 7, and Regulation 7.08, *Standards of Performance for New Process Operations,* Version 4, both State effective January 17, 2018. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the ''**FOR FURTHER INFORMATION CONTACT**'' section of this preamble for more information).

IV. Proposed Action

EPA is proposing to approve changes to the Jefferson County portion of the Kentucky SIP that were provided to EPA through a letter dated March 15, 2018. Specifically, EPA is proposing to

approve the District's Regulation 6.09 version 7 and Regulation 7.08 version 4. The March 15, 2018, SIP revision makes minor and ministerial changes and is intended to clarify the applicability of these regulations, as well as reduce redundancy in the PM and opacity standards. These rule adoptions do not contravene federal permitting requirements or existing EPA policy, nor will they impact the NAAQS or interfere with any other applicable requirement of the Act.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: February 20, 2019.

Mary S. Walker,

Acting Regional Administrator, Region 4.

[FR Doc. 2019–03851 Filed 3–1–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket Nos. 18–335, 11–39; FCC 19–12]

Truth in Caller ID

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes rules to implement these recently adopted amendments which expand and clarify the Act's prohibition on the use of misleading and inaccurate caller ID information. Specifically, this document proposes and seeks comment on modifications to the Commission's current Truth in Caller ID rules that largely track the language of the recent statutory amendments. The document also invites comment on what other changes to our Truth in Caller ID rules the Commission can make to better prevent inaccurate or misleading caller ID information from harming consumers. In doing so, the Commission takes another significant step in its multi-pronged approach to ending malicious caller ID spoofing.

DATES: Comments are due on or before April 3, 2019, and reply comments are due on or before May 3, 2019.

ADDRESSES: You may submit comments, identified by WC Docket Nos. 18–335 and 11–39, by any of the following methods:

- *Federal Communications Commission's website: http://apps.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see section III in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Wireline Competition Bureau, Competition Policy Division, Alex Espinoza, at (202) 418–0849, or *alex.espinoza@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's notice of proposed rulemaking (*NPRM*) in WC Docket Nos. 18–335 and 11–39, adopted on February 14, 2019 and released on February 15, 2019. The full text of this document is available for public inspection during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW, Room CY–A257, Washington, DC 20554. It is available on the Commission's website at *https://www.fcc.gov/document/fcc-seeks-combat-illegal-spoofed-texts-international-calls*.

I. Implementing New Statutory Spoofing Prevention Authority

1. As the Commission did when it initially adopted the Truth in Caller ID Act rules, in proposing rules to implement the recent amendments to section 227(e) of the Act, we largely track the relevant statutory language. We seek comment on our proposals to implement the new statutory language in our rules, generally, and with regard to each specific issue addressed below.

A. Communications Originating Outside the United States

2. First, consistent with the recent amendments to section 227(e), we propose to extend the reach of our caller ID spoofing rules to include communications originating from outside the United States to recipients

within the United States. We seek comment on this proposal. The Truth in Caller ID Act was limited to calls made within the United States; however, as the *2011 Commission Report* to Congress explained, caller ID spoofing ''directed by people and entities outside the United States can cause great harm.'' Six years later, the 2017 Senate Report recognized an increase in fraud committed through caller ID spoofing originating from outside the United States. Incorporating this statutory change into our Truth in Caller ID rules will allow us to bring enforcement actions that allege both statutory and rule violations against bad actors who seek out victims in this country, regardless of where the communications originate.

3. We believe that the statutory language is clear and that mirroring that language will avoid creating ambiguity from any differences between the text of the statute and of our rules. For example, we interpret the term ''person'' in amended section 227(e) to have the same meaning as the Commission determined ''person'' to have in the *2011 Truth in Caller ID Order,* 76 FR 43196 (July 20, 2011). Do commenters agree? Is there other language we should consider adopting to implement this provision of the statute? Are there nuances to the statutory language that we should account for? If so, what are they and how should we incorporate such nuances into our rules?

B. Expanding Scope of Covered Communications

4. Also consistent with section 227(e) as amended, we propose to amend our rules to incorporate the phrase ''in connection with any voice service or text messaging service'' into the prohibition on causing ''any caller identification service to transmit or display misleading or inaccurate caller identification information.'' We seek comment on this proposal.

5. The current prohibition on caller ID spoofing in § 64.1604(a) of our rules does not specify that spoofing in connection with ''any telecommunications service or interconnected VoIP service'' is covered by the rule. However, because we are now proposing to include a wider universe of communications services within the prohibition on caller ID spoofing, we believe that explicitly identifying the services at issue better tracks the language of the statute and provides more direct notice to covered entities. Do commenters agree with this approach? Are there alternatives that we should consider? Does the phrase ''in connection with'' that precedes the phrase ''any voice or text messaging service'' warrant clarification or interpretation in our revised rules?

C. Definitions

6. We also propose to adopt definitions of ''text message,'' ''text messaging service,'' and ''voice service'' and to revise the definitions of ''caller identification information,'' and ''caller identification service'' to implement Congress' intent to expand the scope of the prohibition on harmful caller ID spoofing. We seek comment on each proposed new or revised definition and invite commenters to propose different language to better reflect Congress' intent with respect to the expanded scope of covered communications. We propose to include these definitions in the definitions section of subpart P to our part 64 rules. We seek comment on this proposal and invite commenters to identify any unidentified consequences of that placement.

7. *Text Message.* Section 227(e) as amended defines the term ''text message'' as a ''message consisting of text, images, sounds, or other information that is transmitted to or from a device that is identified as the receiving or transmitting device by means of a 10-digit telephone number or N11 service code.'' Congress further clarified that the term explicitly includes ''a short message service (SMS) message and a multimedia message service (MMS) message'' but excludes ''a real-time, two-way voice or video communication'' or ''a message sent over an IP-enabled messaging service to another user of the same messaging service, except for [an SMS or MMS message].'' We propose to adopt a definition of ''text message'' that mirrors this statutory language. We seek comment on this proposal and on each component of this definition.

8. Is our proposed definition sufficiently inclusive to capture all types of text messages that could be used for prohibited spoofing activity (but excluding messages that fall within the express statutory exclusions)? The definition would encompass messages that include ''text, images, sounds, or other information.'' Are commenters aware of examples of ''information'' that is not text, images or sounds that could comprise the content of a covered text message today, or did Congress include the phrase ''other information'' out of an abundance of caution to be as inclusive as possible given rapid changes in technology? We seek comment on any examples that may now, or in the future, exist and whether such examples should be identified and included in our rules to clarify the term ''other information.''

9. The definition of text message in both section 227(e) as amended and in our proposed rules specifically include SMS and MMS as types of covered text messages. In amending section 227(e), Congress did not define SMS or MMS, nor are there definitions of SMS or MMS contained in the Commission rules. Should we include definitions of SMS and MMS in our Truth in Caller ID rules? In our recent *Wireless Messaging Service Declaratory Ruling,* 84 FR 5008 (Feb. 20, 2019), we described SMS as a ''wireless messaging service'' that ''enables users to send and receive short text messages, typically 160 characters or fewer, to or from mobile phones and can support a host of applications.'' At the same time, we recognized that MMS is ''an extension of the SMS protocol and can deliver a variety of media, and enables users to send pictures, videos, and attachments over wireless messaging channels.'' We believe that our previous description of SMS and MMS are consistent with Congress' use of the terms in amending section 227(e). Do commenters agree? If not, why not? Should we adopt specific definitions or are the terms sufficiently well understood that we need not adopt definitions? If we do adopt definitions for SMS and MMS, should we use the descriptions of SMS and MMS set forth in the *Wireless Messaging Service Declaratory Ruling* as the definitions? Are there refinements we should make to those descriptions?

10. Are there other types of text messages besides SMS and MMS that we should explicitly include in the definition of text message? For instance, Rich Communication Services (RCS), an IP-based asynchronous messaging protocol, is the next-generation SMS. Should we explicitly include RCS in our definition of ''text message''? If so, should we include a definition of RCS in our rules, and what should that definition be?

11. Like section 227(e) as amended, our proposed definition of text message is limited to messages that are ''transmitted to or from a device that is identified as the receiving or transmitting device by means of a 10-digit telephone number or N11 service code.'' The Commission has previously described N11 services as ''abbreviated dialing arrangements that allow telephone users to connect with a particular node in the network by dialing only three digits.'' We believe that our previous description of N11 service codes is consistent with Congress' use of the term in amending section 227(e). Do commenters agree? If

not, why not? Should we adopt a definition of N11 service code? If so, should we codify our previous description? Are there refinements we should make to that description?

12. Section 227(e) as amended excludes from the definition of ''text message'' ''real-time, two-way voice or video communications.'' By proposing to explicitly exclude ''real-time, two-way voice or video communications'' in our proposed definition of ''text message,'' we track the statutory definition. Should we clarify in our rules what ''real-time, two-way voice or video communications'' means for the purpose of being excluded from the term ''text message''? We invite commenters to offer specific clarifying language. We believe that ''real-time, two-way voice'' communications that are transmitted by means of a 10-digit telephone number or N11 service code are excluded from the definition of text message because they are included in the definition of ''voice service.'' We seek comment on that understanding. We also seek comment on whether there are real-time, two-way video communications that are transmitted by means of a 10-digit telephone number or N11 service code that are excluded from the definition of text message and not encompassed by the definition of voice service.

13. Section 227(e) as amended also excludes from the definition of ''text message'' ''a message sent over an IP-enabled messaging service to another user of the same messaging service.'' By tracking the statutory definition of ''text message,'' our proposed definition incorporates that exclusion. We believe we should interpret this exclusion to include non-MMS or SMS messages sent using IP-enabled messaging services such as iMessage, Google Hangouts, WhatsApp, and Skype. For instance, a message sent from one computer to another computer using WhatsApp, or the ''chat'' function on Google Hangouts would appear to be an IP-enabled messaging service between users of the same messaging service under the second exclusion in the statutory definition of ''Text Message.'' Likewise, text communications between or among two or more Skype users or iMessages between or among iPhone users would also not appear to be covered. Do commenters agree? If not, why not? What other IP-messaging services should we recognize as falling within the scope of this exclusion? Should we include specific examples in our rules? Will the scope of this exclusion, as we propose to interpret it, allow for adequate enforcement against misleading or inaccurate text messages or provide a safe harbor for bad actors to exploit?

14. We also seek comment on whether there are other messages consisting of forms of text, visual, audio, or other information transfer using telephone numbers or N11 codes that we should exclude from the definition of ''text message'' beyond those specifically excluded in section 227(e) as amended. We invite commenters to identify any such text message types, and to explain why we should exclude them. Commenters arguing for specific exclusions should explain why, in their view, adding exclusions would be consistent with congressional intent.

15. We do not believe that the new statutory definition of ''text message'' or any of the other recent amendments to section 227(e) regarding text messages affects the Commission's finding that text messages are ''calls'' for purposes of section 227(b) which, among other things, places limits on calls made using any automatic telephone dialing system or artificial or prerecorded voice. Congress placed the new definition of ''text message'' in section 227(e) rather than in section 227(a), which contains definitions generally applicable throughout section 227. We therefore see nothing in section 227(e) as amended to suggest that Congress intended to disturb the Commission's long-standing treatment of text messages under section 227(b), which has been in place since 2003. We seek comment on this view.

16. *Text Messaging Service.* Section 227(e) as amended defines a ''text messaging service'' as ''a service that enables the transmission or receipt of a text message, including a service provided as part of or in connection with a voice service.'' We propose to adopt this same definition as part of our Truth in Caller ID rules and seek comment on this proposal. Maintaining consistency with the statutory definition of text messaging service for unlawful spoofing prevention is particularly important given that it is only text messages ''sent using a text messaging service'' that Congress includes within the scope of section 227(e) as amended. Do commenters agree? If not, why? We also seek comment on the meaning of ''as part of or in connection with a voice service.'' Should we include clarifying language in our rules for an avoidance of doubt? If so, what language do commenters suggest?

17. In the *Wireless Messaging Service Declaratory Ruling*, we found that SMS and MMS wireless messaging services fall within the statutory definition of ''information service'' rather than ''telecommunications service.'' We do not believe this classification impacts our proposals in this *NPRM* to implement statutory amendments to section 227(e). Do commenters agree? If not, why?

18. *Voice Service.* Section 227(e) as amended defines ''voice service'' as any service that is interconnected with the public switched telephone network and that furnishes voice communications to an end user using resources from the North American Numbering Plan or any successor to the North American Numbering Plan adopted by the Commission under section 251(e)(1). It also explicitly ''includes'' ''transmissions from a telephone facsimile machine, computer, or other device to a telephone facsimile machine.'' We propose to adopt the identical definition of ''voice service'' for purposes of our Truth in Caller ID rules. We seek comment on this proposal. Mirroring the definition contained in section 227(e) as amended will avoid potential confusion that might otherwise occur if our rules contain different wording. Do commenters agree? If not, why not and what alternative definition(s) should we consider?

19. Our existing rules cover calls made using ''telecommunications service'' or ''interconnected VoIP service.'' We propose to interpret the term ''voice service'' to include and be more expansive than ''telecommunications service'' and ''interconnected VoIP service'' as currently defined. Do commenters agree? What are examples of specific voice communications captured by the term ''voice service'' but not by the terms ''telecommunications service'' or ''interconnected VoIP service''?

20. Separately, we seek comment on whether we should explicitly include the terms ''telecommunications service'' and ''interconnected VoIP service'' within the definition of ''voice service.'' Would that provide useful clarity to stakeholders? Are there other services we should specifically include within the definition of ''voice service''?

21. We also seek comment on whether we should explicitly include within the definition of voice service, ''real-time, two-way voice communications'' that are transmitted by means of a 10-digit telephone number or N11 service code? Such communications are explicitly excluded from the definition of ''text message'' in section 227(e) as amended. We think the best way to understand that exclusion is to find that those types of voice communications are encompassed by the definition of ''voice service.'' Do commenters agree? Should we modify our proposed definition of

''voice service'' to explicitly incorporate that understanding? We invite commenters to suggest specific modifications.

22. Relatedly, section 227(e) as amended specifies that communications falling within the ''voice service'' definition must be ''interconnected'' with the public switched telephone network (PSTN). Congress neither defined the term ''interconnected'' for purposes of section 227(e) of the Act nor referred to other statutory provisions or Commission rules where the word ''interconnected'' is used as part of the definition of specific categories of communications. For instance, the Act defines ''interconnected VoIP service'' and ''interconnected service'' in different sections of the statute to identify specific but different services that are covered by such definitions. Similarly, our rules contain definitions for each of these terms. Yet Congress uses only the word ''interconnected'' in defining the scope of voice services covered under amended section 227(e). Indeed, in amending section 227(e), Congress specifically *removed* from the definitions of covered voice services the reference to the definition of ''interconnected VoIP service'' as defined in § 9.3 of the Commission's rules. Consequently, we believe Congress no longer intends to limit the scope of IP-enabled voice services implicated by the section 227(e) prohibition to those meeting the definition of ''interconnected VoIP service.'' We invite comment on this proposed conclusion.

23. In light of this apparent intent by Congress to broaden the definition of voice services subject to the section 227(e) prohibition, should we interpret the term ''interconnected'' as used in the definition of ''voice service'' to include any service that enables voice communications either to the PSTN or from the PSTN, regardless of whether it enables both inbound and outbound communications within the same service. For example, should we include within the definition of ''voice services'' any ''one-way'' VoIP service that connects with the PSTN and uses telephone numbers that separately enable users to make outbound calls to landline or mobile telephones or to receive inbound calls from landline or mobile telephones? Such services are not ''interconnected VoIP'' services because they do not permit users to receive calls originating on the PSTN *and* terminate calls to the PSTN. Should we find that section 227(e) as amended, and our proposed implementing rules reach these ''one-way'' IP-based voice services and any similar IP-based or other technology-based calling capability, whether offered by a service provider, or self-provisioned, as long as they connect with the PSTN and use NANP resources?

24. The *2011 Commission Report* recognized that real-time two-way voice communications between and among closed user groups do not give rise to the same degree of caller ID spoofing concern as ''interconnected VoIP services.'' Because these types of services have no connection to the PSTN, we do not believe Congress intends to reach these types of voice communications, nor do we believe that they fall within the definition of ''voice services.'' We seek comment on this view, and whether we should identify and include specific examples of voice communications that do not fall within the definition of ''voice service'' in our rules.

25. We seek comment on whether we should interpret ''interconnected'' to include both direct and indirect interconnection to the PSTN to account for different methods of interconnection. Are there particular types of voice communications that are susceptive to caller ID spoofing that would not be captured by the definition of ''voice services'' if we fail to interpret ''interconnected'' to include voice services that are indirectly connected to the PSTN? What are those services? Are there reasons not to interpret ''interconnected'' to include both direct and indirect connections to the PSTN?

26. Are there other consequences that flow from our proposed interpretation of ''interconnected'' to the PSTN, including any potential consequences resulting from our use of the term ''voice service provider'' in the context of section 227(b), that we should consider? If we interpret ''interconnected'' as we propose to do, should we expressly include a definition of that interpretation within the definition of ''voice service'' in our rules to provide more specificity about that interpretation? If so, we invite suggestions on how to proceed.

27. Finally, the definition of ''voice service'' in section 227(e) as amended specifically ''includes'' transmissions to a ''telephone facsimile machine'' (fax machine) from a computer, fax machine, or other device. We propose to incorporate this additional specification into our rules. We seek comment on this proposal.

28. *Caller Identification Information and Caller Identification Service.* Consistent with amended section 227(e)(8), we also propose to amend the definition of ''caller identification information'' and ''caller identification service'' in our rules to mirror the amended statutory text. Specifically, we propose to substitute ''voice services'' and ''text message sent using a text messaging service'' for ''telecommunications services'' and ''interconnected VoIP services,'' respectively, currently in each of these definitions. We seek comment on this proposal

29. More generally, with respect to all of our proposals to implement new or revised definitions of covered communications within subpart P of part 64 of our rules, we seek comment on whether there are any other uses of these or related terms within this same subpart, or in other parts of our rules, that overlap, are changed or otherwise affected by the definitions we propose and are not specifically addressed above. If so, we invite commenters to identify these other rules and explain how such rules are impacted.

D. Other Potential Changes to the Rules

30. In addition to the proposals we make above to implement the statutory amendments to section 227(e) adopted in the RAY BAUM'S Act, are there other revisions we should make to our Truth in Caller ID rules to effectuate Congress' intent? For example, are there any other necessary limitations, exceptions, extensions, or clarifications to the proposed rules or our existing rules that we have not addressed that are necessary to implement the amendments to section 227(e)? If so, we seek comment on any such further changes to our rules and why they are necessary. Finally, we do not expect our proposed rules or any alternative rules we may adopt in response to this *NPRM* to impact small businesses. Do commenters agree? ZipDX asks us to broaden the scope of this *NPRM* to consider changes to our rules beyond those necessary to implement section 503 of the RAY BAUM'S Act, and beyond the scope of the section 227(e) as amended. We are committed to attacking deceptive robocalls through all the tools at our disposal but limit our proposals herein to those necessary to meet Congress' statutory deadline to prescribe implementing regulations.

II. Initial Regulatory Flexibility Analysis

31. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in the *NPRM.* The Commission requests written public

comments on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided on the first page of the *NPRM.* The Commission will send a copy of the *NPRM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Proposed Rules

32. RAY BAUM'S Act mandates that the Commission issue rules updating the regulations implementing the Truth in Caller ID Act by September 2019. The Congressional mandate coincides with the need to protect consumers from misleading and inaccurate caller ID spoofing, which can contribute to serious fraud and abuse. In this *NPRM,* we propose to update our rules to implement the changes made to the Communications Act by Congress, by including within their scope: (1) Communications originating outside of the United States and (2) forms of communication such as text messaging any interconnected voice communication services that use North American Numbering Plan (NANP) resources, and fax transmissions.

33. The proposed rule changes directly adopt the language contained in RAY BAUM'S Act: The scope of covered communications now includes those originating outside of the United States, so long as they are directed at recipients within the United States; and the types of services covered are changed from ''telecommunications service'' and ''interconnected VoIP service'' to the more precisely defined ''voice service'' and ''text messaging service,'' with ''voice service'' including any service interconnected with the PSTN and that furnishes voice communications to an end user using NANP resources. The proposed rules do not impose record keeping or reporting obligations on any entity.

B. Legal Basis

34. The proposed action is authorized under the RAY BAUM'S Act, Public Law 115–141, Div. P, 132 Stat. 348, and in sections 1, 4(i), 201(b), 227(e), 251(e) and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 201(b), 227(e), 251(e) and 303.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

35. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules and by the rule revisions on which the *NPRM* seeks comment, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. A ''small-business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

36. *Small Businesses, Small Organizations, Small Governmental Jurisdictions.* Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the SBA's Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States which translates to 28.8 million businesses.

37. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of Aug 2016, there were approximately 356,494 small organizations based on registration and tax data filed by nonprofits with the Internal Revenue Service (IRS).

38. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2012 Census of Governments indicates that there were 90,056 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 37,132 General purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,184 Special purpose governments (independent school districts and special districts) with populations of less than 50,000. The 2012 U.S. Census Bureau data for most types of governments in the local government category shows that the majority of these governments have populations of less than 50,000. Based on this data we estimate that at least 49,316 local government jurisdictions fall in the category of ''small governmental jurisdictions.''

39. *Wired Telecommunications Carriers.* The U.S. Census Bureau defines this industry as ''establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry.'' The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. Census data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small.

40. *Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. The closest applicable NAICS Code category is Wired Telecommunications Carriers. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 shows that 3,117 firms operated for the entire year. Of that total, 3,083 operated with fewer than 1,000 employees. Thus under this category and the associated size standard, the Commission estimates that the majority of local exchange carriers are small entities.

41. *Incumbent LECs.* Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent local exchange services. The closest applicable NAICS Code category is Wired Telecommunications Carriers. Under the applicable SBA size standard, such a business is small if it has 1,500

or fewer employees. U.S. Census Bureau data for 2012 indicate that 3,117 firms operated the entire year. Of this total, 3,083 operated with fewer than 1,000 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by our actions. According to Commission data, one thousand three hundred and seven (1,307) Incumbent Local Exchange Carriers reported that they were incumbent local exchange service providers. Of this total, an estimated 1,006 have 1,500 or fewer employees. Thus using the SBA's size standard the majority of incumbent LECs can be considered small entities.

42. *Competitive Local Exchange Carriers (Competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate NAICS Code category is Wired Telecommunications Carriers and under that size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 indicate that 3,117 firms operated during that year. Of that number, 3,083 operated with fewer than 1,000 employees. Based on these data, the Commission concludes that the majority of Competitive LECS, CAPs, Shared-Tenant Service Providers, and Other Local Service Providers, are small entities. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees. In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees. Also, 72 carriers have reported that they are Other Local Service Providers. Of this total, 70 have 1,500 or fewer employees. Consequently, based on internally researched FCC data, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities.

43. We have included small incumbent LECs in this present RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (*e.g.,* a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent LECs in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

44. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA has developed a definition for Interexchange Carriers. The closest NAICS Code category is Wired Telecommunications Carriers. The applicable size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 indicate that 3,117 firms operated for the entire year. Of that number, 3,083 operated with fewer than 1,000 employees. According to internally developed Commission data, 359 companies reported that their primary telecommunications service activity was the provision of interexchange services. Of this total, an estimated 317 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of interexchange service providers are small entities.

45. *Local Resellers.* The SBA has developed a small business size standard for Telecommunications Resellers which includes Local Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. Under the SBA's size standard, such a business is small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2012 show that 1,341 firms provided resale services during that year. Of that number, all operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these resellers can be considered small entities. According to Commission data, 213 carriers have reported that they are engaged in the provision of local resale services. Of these, an estimated 211 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of Local Resellers are small entities.

46. *Toll Resellers.* The Commission has not developed a definition for Toll Resellers. The closest NAICS Code Category is Telecommunications Resellers. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 show that 1,341 firms provided resale services during that year. Of that number, 1,341 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of these resellers can be considered small entities. According to Commission data, 881 carriers have reported that they are engaged in the provision of toll resale services. Of this total, an estimated 857 have 1,500 or fewer employees. Consequently, the Commission estimates that the majority of toll resellers are small entities.

47. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a definition for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable NAICS Code category is for Wired Telecommunications Carriers as defined above. Under the applicable SBA size standard, such a business is small if it has 1,500 or fewer employees. Census data for 2012 shows that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this category and the associated small business size standard, the majority of Other Toll Carriers can be considered small. According to internally developed Commission data, 284 companies reported that their primary telecommunications service activity was

the provision of other toll carriage. Of these, an estimated 279 have 1,500 or fewer employees. Consequently, the Commission estimates that most Other Toll Carriers are small entities.

48. *Prepaid Calling Card Providers.* The SBA has developed a definition for small businesses within the category of Telecommunications Resellers. Under that SBA definition, such a business is small if it has 1,500 or fewer employees. According to the Commission's Form 499 Filer Database, 500 companies reported that they were engaged in the provision of prepaid calling cards. The Commission does not have data regarding how many of these 500 companies have 1,500 or fewer employees. Consequently, the Commission estimates that there are 500 or fewer prepaid calling card providers that may be affected by the proposed rules.

49. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had employment of 999 or fewer employees and 12 had employment of 1000 employees or more. Thus under this category and the associated size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities.

50. The Commission's own data—available in its Universal Licensing System—indicate that, as of October 25, 2016, there are 280 Cellular licensees that will be affected by our actions today. The Commission does not know how many of these licensees are small, as the Commission does not collect that information for these types of entities. Similarly, according to internally developed Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, Personal Communications Service, and Specialized Mobile Radio Telephony services. Of this total, an estimated 261 have 1,500 or fewer employees, and 152 have more than 1,500 employees. Thus, using available data, we estimate that the majority of wireless firms can be considered small.

51. *Wireless Communications Services.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined ''small business'' for the wireless communications services (WCS) auction as an entity with average gross revenues of $40 million for each of the three preceding years, and a ''very small business'' as an entity with average gross revenues of $15 million for each of the three preceding years. The SBA has approved these small business size standards. *Wireless Telephony.* Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. The closest applicable SBA category is Wireless Telecommunications Carriers (except Satellite) and the appropriate size standard for this category under the SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census Bureau data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had fewer than 1,000 employees and 12 firms had 1,000 employees or more. Thus under this category and the associated size standard, the Commission estimates that a majority of these entities can be considered small. According to Commission data, 413 carriers reported that they were engaged in wireless telephony. Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. Therefore, more than half of these entities can be considered small.

52. *Cable and Other Subscription Programming.* This industry comprises establishments primarily engaged in operating studios and facilities for the broadcasting of programs on a subscription or fee basis. The broadcast programming is typically narrowcast in nature (*e.g.* limited format, such as news, sports, education, or youth-oriented). These establishments produce programming in their own facilities or acquire programming from external sources. The programming material is usually delivered to a third party, such as cable systems or direct-to-home satellite systems, for transmission to viewers. The SBA size standard for this industry establishes as small, any company in this category which has annual receipts of $38.5 million or less. According to 2012 U.S. Census Bureau data, 367 firms operated for the entire year. Of that number, 319 operated with annual receipts of less than $25 million a year and 48 firms operated with annual receipts of $25 million or more. Based on this data, the Commission estimates that the majority of firms operating in this industry are small.

53. *Cable Companies and Systems (Rate Regulation).* The Commission has developed its own small business size standards for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers nationwide. Industry data indicate that there are currently 4,600 active cable systems in the United States. Of this total, all but eleven cable operators nationwide are small under the 400,000-subscriber size standard. In addition, under the Commission's rate regulation rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Current Commission records show 4,600 cable systems nationwide. Of this total, 3,900 cable systems have fewer than 15,000 subscribers, and 700 systems have 15,000 or more subscribers, based on the same records. Thus, under this standard as well, we estimate that most cable systems are small entities.

54. *Cable System Operators (Telecom Act Standard).* The Communications Act, as amended, also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than one percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' There are approximately 52,403,705 cable video subscribers in the United States today. Accordingly, an operator serving fewer than 524,037 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate. Based on available data, we find that all but nine incumbent cable operators are small entities under this size standard. The Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed $250 million, we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

55. *All Other Telecommunications.* The ''All Other Telecommunications'' category is comprised of establishments primarily engaged in providing specialized telecommunications

services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing internet services or voice over internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry. The SBA has developed a small business size standard for All Other Telecommunications, which consists of all such firms with annual receipts of $32.5 million or less. For this category, U.S. Census Bureau data for 2012 shows that there were 1,442 firms that operated for the entire year. Of those firms, a total of 1,400 had annual receipts less than $25 million and 42 firms had annual receipts of $25 million to $49,999,999. Thus, the Commission estimates that the majority of ''All Other Telecommunications'' firms potentially affected by our action can be considered small.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

56. This *NPRM* proposes changes to, and seeks comment on, the Commission's Truth in Caller ID rules. The proposed rules do not contain reporting or recordkeeping requirements, and the proposals adopt no new reporting or recordkeeping requirements.

E. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

57. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.

58. RAY BAUM'S Act does not distinguish between small entities and other entities and individuals. In the *NPRM,* the Commission seeks comment on alternatives to the proposed, rules, and on alternative ways of implementing the proposed rules. The revisions proposed to the Commission's rules are not expected to result in significant economic impact to small entities.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

59. None.

III. Procedural Matters

60. *Comment Filing Procedures.* Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the **DATES** section of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.
- *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

61. *Ex Parte Presentations.* This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with § 1.1206(b). In proceedings governed by § 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

62. *Regulatory Flexibility Analysis.* Pursuant to the Regulatory Flexibility Act (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities of the policies and actions considered in this notice of proposed rulemaking. The text of the IRFA is set forth in section II of this document. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for

comment on the notice of proposed rulemaking. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of this notice of proposed rulemaking, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

63. *Paperwork Reduction Act.* This document does not propose new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burdens for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198.

64. *Contact Person.* For further information about this proceeding, please contact E. Alex Espinoza, FCC Wireline Competition Bureau, Competition Policy Division, Room 5–C211, 445 12th Street SW, Washington, DC 20554, at (202) 418–0849, or *alex.espinoza@fcc.gov.*

IV. Ordering Clauses

65. Accordingly, *it is ordered,* pursuant to sections 1, 4(i), 201(b), 227(e), 251(e) and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 201(b), 227(e), 251(e) and 303, and Public Law 115–141, Div. P, Title V, section 503, 132 Stat. 348 that this notice of proposed rulemaking *is adopted.*

66. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this notice of proposed rulemaking, including the Initial Regulatory Flexibility Analysis (IRFA), to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 64

Communications common carriers, Caller identification information, Telecommunications, Telephone.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 64 as follows:

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

■ 1. The authority citation for part 64 is revised to read as follows:

Authority: 47 U.S.C. 154, 201, 202, 218, 222, 225, 226, 227, 228, 251(e), 254(k), 403(b)(2)(B), (c), 616, 620, 1401–1473; Sec. 5103, Pub. L. 115–141, 132 Stat. 348.

■ 2. Amend § 64.1600 by revising paragraphs (c) and (d) and adding paragraphs (m) through (o) to read as follows:

§ 64.1600 Definitions.

* * * * *

(c) *Caller identification information.* The term ''caller identification information'' means information provided by a caller identification service regarding the telephone number of, or other information regarding the origination of, a call made using a voice service or a text message sent using a text messaging service.

(d) *Caller identification service.* The term ''caller identification service'' means any service or device designed to provide the user of the service or device with the telephone number of, or other information regarding the origination of, a call made using a voice service or a text message sent using a text messaging service.

* * * * *

(m) *Text message.* The term ''text message'':

(1) Means a message consisting of text, images, sounds, or other information that is transmitted to or from a device that is identified as the receiving or transmitting device by means of a 10-digit telephone number or N11 service code;

(2) Includes a short message service (SMS) message, and a multimedia message service (MMS) message; and

(3) Does not include:

(i) A real-time, two-way voice or video communication; or

(ii) A message sent over an IP-enabled messaging service to another user of the same messaging service, except a message described in paragraph (2) of this definition.

(n) *Text messaging service.* The term ''text messaging service'' means a service that enables the transmission or receipt of a text message, including a service provided as part of or in connection with a voice service.

(o) *Voice service.* The term ''voice service'':

(1) Means any service that is interconnected with the public switched telephone network and that furnishes voice communications to an end user using resources from the North American Numbering Plan or any successor to the North American Numbering Plan adopted by the Commission under section 251(e)(1); and

(2) Includes transmissions from a telephone facsimile machine, computer, or other device to a telephone facsimile machine.

■ 3. Amend § 64.1604 by revising paragraph (a) to read as follows:

§ 64.1604 Prohibition on transmission of inaccurate or misleading caller identification information.

(a) No person or entity in the United States, nor any person or entity outside the United States if the recipient is within the United States, shall, with the intent to defraud, cause harm, or wrongfully obtain anything of value, knowingly cause, directly, or indirectly, any caller identification service to transmit or display misleading or inaccurate caller identification information in connection with any voice service or text messaging service.

* * * * *

[FR Doc. 2019–03721 Filed 3–1–19; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[0648–XG791]

Fisheries off West Coast States; Highly Migratory Fisheries; Amendment 6 to Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species; Authorization of Deep-Set Buoy Gear

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS); announcement of public scoping period and request for comments.

SUMMARY: NMFS and the Pacific Fishery Management Council (Council) announce their intent to prepare an EIS, in accordance with the National Environmental Policy Act (NEPA) of 1969, to analyze the potential short- and long-term impacts of the proposed action to authorize deep-set buoy gear under the Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species (HMS FMP) on the human (biological, physical, social, and economic) environment. This notice of

intent to prepare an EIS invites interested parties to provide comments on alternatives to be considered in an EIS and to identify potential issues, concerns, and any reasonable additional alternatives that should be considered.

DATES: Written comments on the scope of the analysis will be accepted through April 3, 2019. Written, faxed, or emailed comments must be received by 5 p.m. Pacific Daylight Time (PDT) on April 3, 2019. Public comments will also be accepted during a webinar scheduled for 1 p.m. to 3 p.m. PDT, March 26, 2019. Please notify Lyle Enriquez (see **FOR FURTHER INFORMATION CONTACT**, below) by March 19, 2019, if you plan to attend the webinar. Instructions for connecting or calling into the webinar will be emailed to meeting participants. Accommodations for persons with disabilities are available; accommodation requests should be directed to Lyle Enriquez at least 10 working days prior to the webinar. Additionally, please note that public scoping for this proposed action will continue through regular meetings of the Council and its advisory bodies (see: *http://www.pcouncil.org/council-operations/council-meetings/future-meetings/*).

ADDRESSES: You may submit comments on the scope of this EIS by any of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2019-0015*
2. Click the ''Comment Now!'' icon, complete the required fields, and
3. Enter or attach your comments.

—OR—

• *Mail:* Submit written comments to *Lyle.Enriquez@noaa.gov,* NMFS West Coast Region Long Beach Office, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802. Include the identifier ''NOAA–NMFS–2019–0015'' in the comments.

Instructions: Comments must be submitted by one of the above methods to ensure they are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of this document can be obtained from *http://www.regulations.gov,* docket NOAA–NMFS–2019–0015, or by contacting NMFS West Coast Region Long Beach Office, 501 W Ocean Blvd., Suite 4200, Long Beach, CA 90802, or *WCR.HMS@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Lyle Enriquez, NMFS, 562–980–4025, *Lyle.Enriquez@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

After a series of initial research and exempted fishing permit trials of deep-set buoy gear, (including both standard and linked configurations) the Council decided to consider authorizing the gear to be fished in the exclusive economic zone (EEZ) off the U.S. west coast under the HMS FMP. The initial trials indicate that this innovative gear-type has infrequent protected species (including sea turtles, marine mammals, and seabirds) interactions and finfish bycatch, and it may contribute to an economically viable U.S. west coast swordfish fishery. Currently, only two other fishing gears are authorized for targeting swordfish in the EEZ off the U.S. west coast: Harpoon and drift gillnet. Participation in the drift gillnet fleet has declined considerably over the last two decades, with between 17 and 23 vessels delivering swordfish landings to U.S. west coast ports each year since 2014. Fewer than 21 harpoon vessels made landings each year since 2014. The harpoon fishery has historically been a low-volume fishery compared to the drift gillnet fishery.

Purpose and Need for the Proposed Action

The purpose and need as determined by the Council during its November 2018 meeting are as follows:

• The purpose of the proposed action is to authorize the use of deep-set buoy gear as an additional fishing gear in the U.S. west coast commercial swordfish fishery that minimizes bycatch and incidental mortality of finfish and protected species (including sea turtles, marine mammals, and seabirds) to the extent practicable while maximizing the potential for an economically viable fishery.

• The proposed action is needed to authorize deep-set buoy gear as a new gear type as a component of a U.S. west coast swordfish fishery that effectively addresses the 10 National Standards (NS) for Conservation and Management included in the Magnuson Stevens Act, Section 301, in particular NS One (optimum yield) and Nine (minimize bycatch).

Deep-Set Buoy Gear Configurations and Operations

Deep-set buoy gear is an umbrella term referring to two distinct gear configurations. These configurations include standard buoy gear and linked buoy gear. An individual piece of standard buoy gear consists of a vertical monofilament mainline suspended from a buoy-array with a terminal weight. Up to three gangions with hooks may be attached to the mainline at a minimum depth of 90 meters (295 feet). An individual piece of linked buoy gear consists of a monofilament mainline which extends vertically from a buoy-array (either directly or from a minimum 50 foot poly-line extender) to a weight; then horizontally to a second weight; then vertically to a minimum 50 foot poly-line extender attached to a second buoy-array. Up to three gangions with hooks may be connected to each horizontal section of the mainline, all of which must be fished below 90 meters. The pieces may be linked together by the mainline, which is serviceable between each piece of linked buoy gear and must be suspended between links below a depth of 50 feet. No more than 10 sections of linked buoy gear may be deployed at any one time, with no more than three hooks per section.

Both configurations include the following specifications and operational criteria:

• The surface buoy flotation and strike detection array must consist of a minimum of three buoys (a minimum 45 pound buoyancy non-compressible hard ball, a minimum 6 pound buoyancy buoy, and a strike detection buoy), with no more than six feet of line between adjacent buoys, all connected in-line by a minimum of ⅜ inch diameter line and no use of buoy tether attachments (*e.g.,* non-streamlined gear with loops and/or dangling components). Standard and terminal linked buoy-arrays must include a locator flag, a radar reflector, and vessel/fisher identification compliant with all current state requirements and regulations;

• Weights must be a minimum of 3.6 kilograms;

• Lines connecting surface buoys must be at least ⅜ of an inch in diameter;

• Minimum size 16/0 circle hooks with not more than 10° offset;

• A vessel may deploy no more than ten pieces of standard or linked buoy gear one time, with no more than three hooks per piece;

• All pieces of gear must remain within a five nautical mile diameter circle and the vessel may be no more than three nautical miles from the nearest piece of gear. These specifications allow for active tending;

• Gear must be deployed prior to local sunrise and onboard the vessel no later than three hours after local sunset;

• Gear types other than deep-set buoy gear may be used on the same trip when deep-set buoy gear is used as long as the deep-set buoy gear is actively tended. This limits the gears with which fishermen could concurrently fish with deep-set buoy gear and maintain maneuverability to allow for active tending or staying within the active tending boundary or both. Other gears may be set and retrieved on the way out to and returning from sea, and deep-set buoy gear fished and actively tended in between, potentially at a large distance from the other gear.

Alternatives

A detailed description of the alternatives adopted by the Council on November 7, 2018, can be found here: *https://www.pcouncil.org/wp-content/uploads/2019/02/J1a_NMFS_Rpt1_MAR2019BB.pdf.* The following description summarizes the scope of the alternatives currently being considered by NMFS and the Council. The range of alternatives that the Council adopted includes a No Action Alternative and two action alternatives (*i.e.,* Alternative 1 and Alternative 2). The action area encompasses the U.S. west coast EEZ between the Mexico/United States border to the South and the Oregon/Washington border to the North. Alternative 1 is to authorize deep-set buoy gear under an open access permit. Alternative 2 is to authorize the gear as an open access permit for the action area, except for an area off of Southern California East of 120°28′18″ W longitude, which would be authorized through a limited entry permit or endorsement. The Council advised analyzing the impacts of authorizing up to 500 permits under each action alternative.

Under Alternative 2, the Council adopted five sub-options pertaining to the number and timing of limited entry permits to be issued in the Southern California Bight. These options are as follows:

1. Not more than 25 permits per year, not to exceed 300 total;
2. Not more than 50 permits per year, not to exceed 300 total;
3. Not more than 100 permits per year, not to exceed 300 total;
4. Not more than 300 permits maximum; and
5. Up to 50 permits issued in the first permit year, and up to 25 permits issued annually in subsequent years until either (a) a maximum of 300 permits are issued, (b) NMFS determines less than 300 are necessary to ensure compliance with the Endangered Species Act and Marine Mammal Protection Act, or (c) the Council recommends to NMFS that less than 300 permits are necessary to meet stakeholder needs.

The Council selected Alternative 2, Option 5 as its preliminary preferred alternative (PPA) on November 7, 2018. On November 7, 2018, the Council also selected a range of options for limited entry qualifying criteria (*i.e.,* including ranked criteria for some options) for limited entry permits to be issued under Alternative 2. These options would assign higher permit issuance priority to persons with demonstrated swordfish fishing experience or permit possession history. Once priority-ranked permits are issued under these options, any remaining permits would be issued on a first-come, first-served basis.

Preliminary Identification of Environmental Issues

A principal objective of the scoping and public input process is to identify potentially significant impacts to the human environment that should be analyzed in depth in the EIS. Information and analysis prepared for this action also may be used for scoping future swordfish harvest and management measure actions to help decide whether to prepare an Environmental Assessment or EIS.

Public Scoping Process

Public scoping occurs throughout the Council's decision-making process. All decisions during the Council process benefit from written and oral public comments delivered prior to or during Council meetings. These public comments are integral to scoping for developing this EIS. The Council began considering the proposed action at their March 2016 meeting, and they developed a range of alternatives during their June 2016, March 2017, and June 2018 meetings. During the November 2018 meeting, the Council adopted a final range of alternatives, including qualifying criteria for limited entry program options, and selected a preliminary preferred alternative. Council meetings in 2019 that offer additional opportunities for public involvement include: The March 5–12 meeting in Vancouver, Washington (Hilton Vancouver Washington, 301 W Sixth Street, Vancouver, WA 98660), and the June 18–25 meeting in San Diego, California (Doubletree by Hilton San Diego (7450 Hazard Center Drive, San Diego, CA 92108). For further information on these meetings, visit the Council's website, *http://www.pcouncil.org/council-operations/council-meetings/future-meetings/.*

Dated: February 22, 2019.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2019–03493 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 84, No. 42

Monday, March 4, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0005]

Environmental Impact Statement for Predator Damage Management in Idaho

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service plans to prepare an environmental impact statement analyzing alternatives for predator damage management in Idaho.

FOR FURTHER INFORMATION CONTACT: Mr. Kirk Gustad, Wildlife Services, APHIS, USDA, 9134 West Blackeagle Drive, Boise, ID 83709; (208) 373–1630.

SUPPLEMENTARY INFORMATION: The Animal and Plant Health Inspection Service (APHIS) intends to prepare an environmental impact statement (EIS) to address alternatives for APHIS Wildlife Services' involvement in managing damage and threats to livestock and other domestic animals, agricultural resources, property, natural resources, and human health and safety associated with predators in Idaho. The scope of the EIS is intended to include management of damage and conflicts associated with coyotes, gray wolves, black bears, grizzly bears, mountain lions, bobcats, red foxes, striped skunks, raccoons, badgers, feral and free-ranging dogs, common ravens, and black-billed magpies. Feral and free-ranging cats, feral swine, western spotted skunks, mink, long-tailed weasels, short-tailed weasels, American crows, bald eagles, and golden eagles are associated with conflicts on rare occasions and also will be addressed in the analysis.

We anticipate initiating public scoping for the EIS in May 2019. Once completed, the EIS will replace APHIS Wildlife Services' regional environmental assessments on predator damage management in Southern Idaho and in Northern and Central Idaho, and the environmental assessment on gray wolf damage management in Idaho.

Done in Washington, DC, on February 27, 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–03834 Filed 3–1–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–088]

Steel Racks and Parts Thereof From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that steel racks and parts thereof (steel racks) from the People's Republic of China (China) are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation (POI) October 1, 2017, through March 31, 2018.

DATES: Applicable March 4, 2019.

FOR FURTHER INFORMATION CONTACT: Patrick O'Connor or Maliha Khan, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0989 or (202) 482–0895, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on July 17, 2018.[1] On October 24, 2018, Commerce postponed the preliminary determination of this investigation until January 19, 2019.[2] Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[3] If the new deadline falls on a non-business day, in accordance with Commerce's practice, the deadline will become the next business day. The revised deadline for the preliminary determination is now February 25, 2019. For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The products covered by this investigation are steel racks from China. For a complete description of the scope of this investigation, *see* Appendix I.

[1] *See Steel Racks from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 83 FR 33195 (July 17, 2018) (*Initiation Notice*).

[2] *See Steel Racks and Parts Thereof from the People's Republic of China: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation,* 83 FR 53606 (October 24, 2018).

[3] *See* memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[4] *See* Memorandum, ''Steel Racks from the People's Republic of China: Decision Memorandum for the Preliminary Determination of Sales at Less Than Fair Value'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Scope Comments

In accordance with the preamble to Commerce's regulations,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (scope).[6] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice,* as well as additional language proposed by the petitioner. For a summary of the product coverage comments and rebuttal responses submitted to the record of this investigation, and accompanying discussion and analysis of comments timely received, *see* Scope Decision Memorandum.[7] Based on comments and rebuttal comments received, Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the revised scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Because China is a non-market economy country within the meaning of section 771(18) of the Act, Commerce has calculated normal value (NV) in accordance with section 773(c) of the Act. Furthermore, pursuant to sections 776(a) and (b) of the Act, Commerce preliminarily has relied upon facts otherwise available, with adverse inferences, for the China-wide entity, which includes Jiangsu Kingmore Storage Equipment Manufacturing Co., Ltd., Nanjing Huade Storage Equipment Manufacturing Co., Ltd., Nanjing Inform Storage Equipment (Group) Co., Ltd., Tangshan Apollo Energy Equipment Company, Ltd., Xiamen PDF Co., Ltd. and Zhangzhou URB Fabricating Co., Ltd. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,*[8] Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[9]

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter	Producer	Estimated weighted-average dumping margin (percent)
Nanjing Dongsheng Shelf Manufacturing Co., Ltd	Nanjing Dongsheng Shelf Manufacturing Co., Ltd	18.08
Ateel Display Industries (Xiamen) Co., Ltd	Ateel Display Industries (Xiamen) Co., Ltd	18.08
CTC Universal (Zhangzhou) Industrial Co., Ltd	CTC Universal (Zhangzhou) Industrial Co., Ltd	18.08
David Metal Craft Manufactory Ltd	David Metal Craft Manufactory Ltd	18.08
Guangdong Wireking Housewares and Hardware Co., Ltd	Guangdong Wireking Housewares and Hardware Co., Ltd	18.08
Hebei Minmetals Co., Ltd	Hebei Wuxin Garden Products Co., Ltd	18.08
Hebei Minmetals Co., Ltd	Huanghua Xinxing Furniture Co., Ltd	18.08
Hebei Minmetals Co., Ltd	Huanghua Xingyu Hardware Products Co., Ltd	18.08
Hebei Minmetals Co., Ltd	Huangua Qingxin Hardware Products Co., Ltd	18.08
Hebei Minmetals Co., Ltd	Huangua Haixin Hardware Products Co., Ltd	18.08
Hebei Minmetals Co., Ltd	Huanghua Hualing Hardware Products Co., Ltd	18.08
i-Lift Equipment Ltd	Yuanda Storage Equipment Ltd	18.08
Jiangsu Nova Intelligent Logistics Equipment Co., Ltd	Jiangsu Nova Intelligent Logistics Equipment Co., Ltd	18.08
Johnson (Suzhou) Metal Products Co., Ltd	Johnson (Suzhou) Metal Products Co., Ltd	18.08
Master Trust (Xiamen) Import and Export Co., Ltd	Zhangzhou Hongcheng Hardware & Plastic Industry Co., Ltd	18.08
Nanjing Ironstone Storage Equipment Co., Ltd	Jiangsu Baigeng Logistics Equipments Co., Ltd	18.08
Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd	Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd	18.08
Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd	Jiangsu Kingmore Storage Equipment Manufacturing Co., Ltd	18.08
Ningbo Beilun Songyi Warehouse Equipment Manufacturing Co., Ltd.	Ningbo Beilun Songyi Warehouse Equipment Manufacturing Co., Ltd.	18.08
Ningbo Xinguang Rack Co., Ltd	Ningbo Xinguang Rack Co., Ltd	18.08
Qingdao Rockstone Logistics Appliance Co., Ltd	Qingdao Rockstone Logistics Appliance Co., Ltd	18.08
Redman Corporation	Redman Corporation	18.08
Redman Import & Export Limited	Redman Corporation	18.08
Suzhou (China) Sunshine Hardware & Equipment Imp. & Exp. Co. Ltd.	Changzhou Tianyue Storage Equipment Co., Ltd	18.08
Suzhou (China) Sunshine Hardware & Equipment Imp. & Exp. Co. Ltd.	Ningbo Beilun Songyi Warehouse Equipment Manufacturing Co., Ltd.	18.08
Tianjin Master Logistics Equipment Co., Ltd	Tianjin Master Logistics Equipment Co., Ltd	18.08
Waken Display System Co., Ltd	CTC Universal (Zhangzhou) Industrial Co., Ltd	18.08
Xiamen Aifeimetal Manufacturing Co., Ltd	Xiamen Aifeimetal Manufacturing Co., Ltd	18.08
Xiamen Baihuide Manufacturing Co., Ltd	Xiamen Baihuide Manufacturing Co., Ltd	18.08
Xiamen Ever Glory Fixtures Co., Ltd	Fujian First Industry and Trade Co., Ltd	18.08
Xiamen Ever Glory Fixtures Co., Ltd	Fujian Ever Glory Fixtures Co., LTD	18.08
Xiamen Ever Glory Fixtures Co., Ltd	Xiamen Ever Glory Fixtures Co., Ltd	18.08
Xiamen Golden Trust Industry & Trade Co., Ltd	Xiamen Golden Trust Industry & Trade Co., Ltd	18.08

[5] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[6] *See Initiation Notice.*

[7] *See* Memorandum, ''Steel Racks from the People's Republic of China: Preliminary Scope Decision'' (Scope Decision Memorandum), dated concurrently with this preliminary determination.

[8] *See Initiation Notice.*

[9] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy Bulletin 05.1), available on Commerce's website at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

Exporter	Producer	Estimated weighted-average dumping margin (percent)
Xiamen Kingfull Imp and Exp Co., Ltd (d.b.a) Xiamen Kingfull Displays Co., Ltd.	Xiamen Huiyi Beauty Furniture Co., Ltd	18.08
Xiamen Kingfull Imp and Exp Co., Ltd (d.b.a) Xiamen Kingfull Displays Co., Ltd.	Xiamen LianHong Industry and Trade Co., Ltd	18.08
Xiamen LianHong Industry and Trade Co., Ltd	Xiamen LianHong Industry and Trade Co., Ltd	18.08
Xiamen Luckyroc Industry Co., Ltd	Xiamen Luckyroc Storage Equipment Manufacture Co., Ltd	18.08
Xiamen Meitoushan Metal Product Co., Ltd	Xiamen Meitoushan Metal Product Co., Ltd	18.08
Xiamen Power Metal Display Co., Ltd	Xiamen Power Metal Display Co., Ltd	18.08
Xiamen XinHuiYuan Industrial & Trade Co., Ltd	Xiamen XinHuiYuan Industrial & Trade Co., Ltd	18.08
Xiamen Yiree Display Fixtures Co., Ltd	Xiamen Yiree Display Fixtures Co., Ltd	18.08
Zhangjiagang Better Display Co., Ltd	Zhangjiagang Better Display Co., Ltd	18.08
China-wide Entity		144.50

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as discussed below. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted average amount by which normal value exceeds U.S. price, as indicated in the table above as follows: (1) For the producer/exporter combinations listed in the table above, the cash deposit rate is equal to the estimated weighted-average dumping margin listed for that combination in the table; (2) for all combinations of China producers/exporters of merchandise under consideration that have not established eligibility for their own separate rates, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the China-wide entity; and (3) for all third-county exporters of the merchandise under consideration not listed in the table above, the cash deposit rate is the cash deposit rate applicable to the China producer/exporter combination (or the China-wide entity) that supplied that third-country exporter.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion CVD proceeding when CVD provisional measures are in effect. However, Commerce has not made a preliminary affirmative determination for a domestic subsidy pass-through adjustment in this AD investigation, nor has it found export subsidies in the companion CVD investigation. Therefore, Commerce made no offsets to the estimated weighted-average dumping margin for purposes of calculating the appropriate cash deposit rate.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with this preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments, on all issues other than scope issues, may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this investigation, unless the Secretary alters the time limit. Rebuttal case briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs.[10]

Interested parties may address Commerce's preliminary scope determination in scope briefs which may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the publication of the preliminary AD determination in the **Federal Register**. Rebuttal scope briefs, limited to issues raised in scope briefs, may be submitted no later than five days after the deadline date for scope briefs. Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary

[10] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

determination, a request for such postponement is made by the petitioner. Pursuant to 19 CFR 351.210(e)(2), Commerce requires that requests by respondents for postponement of a final antidumping determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On December 10, 2018, pursuant to 19 CFR 351.210(b)(2)(ii) and e(2), Nanjing Dongsheng requested that Commerce postpone the final determination, and that provisional measures be extended to a period not to exceed six months.[11] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii) and (e)(2), because (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make the final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.[12]

International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its preliminary determination of sales at LTFV. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: February 25, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is steel racks and parts thereof, assembled, to any extent, or unassembled, including but not limited to, vertical components (*e.g.,* uprights, posts, or columns), horizontal or diagonal components (*e.g.,* arms or beams), braces, frames, locking devices (*e.g.,* end plates and beam connectors), and accessories (including, but not limited to, rails, skid channels, skid rails, drum/coil beds, fork clearance bars, pallet supports, row spacers, and wall ties).

Subject steel racks and parts thereof are made of steel, including, but not limited to, cold and/or hot-formed steel, regardless of the type of steel used to produce the components and may, or may not, include locking tabs, slots, or bolted, clamped, or welded connections. Subject steel racks have the following physical characteristics:

(1) Each steel vertical and horizontal load bearing member (*e.g.,* arms, beams, posts, and columns) is composed of steel that is at least 0.044 inches thick;

(2) Each steel vertical and horizontal load bearing member (*e.g.,* arms, beams, posts, and columns) is composed of steel that has a yield strength equal to or greater than 36,000 pounds per square inch;

(3) The width of each steel vertical load bearing member (*e.g.,* posts and columns) exceeds two inches; and

(4) The overall depth of each steel roll-formed horizontal load bearing member (*e.g.,* beams) exceeds two inches.

In the case of steel horizontal load bearing members other than roll-formed (*e.g.,* structural beams, Z-beams, or cantilever arms), only the criteria in subparagraphs (1) and (2) apply to these horizontal load bearing members. The depth limitation in subparagraph (4) does not apply to steel horizontal load bearing members that are not roll-formed.

Steel rack components can be assembled into structures of various dimensions and configurations by welding, bolting, clipping, or with the use of devices such as clips, end plates, and beam connectors, including, but not limited to the following configurations: (1) Racks with upright frames perpendicular to the aisles that are independently adjustable, with positive-locking beams parallel to the aisle spanning the upright frames with braces; and (2) cantilever racks with vertical components parallel to the aisle and cantilever beams or arms connected to the vertical components perpendicular to the aisle. Steel racks may be referred to as pallet racks, storage racks, stacker racks, retail racks, pick modules, selective racks, or cantilever racks and may incorporate moving components and be referred to as pallet-flow racks, carton-flow racks, push-back racks, movable-shelf racks, drive-in racks, and drive-through racks. While steel racks may be made to ANSI MH16.l or ANSI MH16.3 standards, all steel racks and parts thereof meeting the description set out herein are covered by the scope of this investigation, whether or not produced according to a particular standard.

The scope includes all steel racks and parts thereof meeting the description above, regardless of

(1) other dimensions, weight, or load rating;

(2) vertical components or frame type (including structural, roll-form, or other);

(3) horizontal support or beam/brace type (including but not limited to structural, roll-form, slotted, unslotted, Z-beam, C-beam, L-beam, step beam, and cantilever beam);

(4) number of supports;

(5) number of levels;

(6) surface coating, if any (including but not limited to paint, epoxy, powder coating, zinc, or other metallic coatings);

(7) rack shape (including but not limited to rectangular, square, corner, and cantilever);

(8) the method by which the vertical and horizontal supports connect (including but not limited to locking tabs or slots, bolting, clamping, and welding); and

(9) whether or not the steel rack has moving components (including but not limited to rails, wheels, rollers, tracks, channels, carts, and conveyors).

Subject merchandise includes merchandise matching the above description that has been finished or packaged in a third country. Finishing includes, but is not limited to, coating, painting, or assembly, including attaching the merchandise to another product, or any other finishing or assembly operation that would not remove the merchandise from the scope of the investigation if performed in the country of manufacture of the steel racks and parts thereof. Packaging includes packaging the merchandise with or without another product or any other packaging operation that would not remove the merchandise from the scope of the investigation if performed in the country of manufacture of the steel racks and parts thereof.

Steel racks and parts thereof are included in the scope of this investigation whether or not imported attached to, or included with, other parts or accessories such as wire decking, nuts, and bolts. If steel racks and parts thereof are imported attached to, or included with, such non-subject merchandise, only the steel racks and parts thereof are included in the scope.

The scope of this investigation does not cover: (1) Decks, *i.e.,* shelving that sits on or fits into the horizontal supports to provide the horizontal storage surface of the steel racks; (2) wire shelving units, *i.e.,* units made from wire that incorporate both a wire deck and wire horizontal supports (taking the place of the horizontal beams and braces) into a single piece with tubular collars that slide over the posts and onto plastic sleeves snapped on the posts to create a finished unit; (3) pins, nuts, bolts, washers, and clips used as connecting devices; and (4) non-steel components.

Specifically excluded from the scope of this investigation are any products covered by Commerce's existing antidumping and countervailing duty orders on boltless steel

[11] *See* Letter from Dongsheng, ''Steel Racks from the People's Republic of China—Request for Extension of Final Determination and Provisional Measures,'' dated December 10, 2018, (''Dongsheng Extension Request'').

[12] *See* 19 CFR 351.210(e).

shelving units prepackaged for sale from the People's Republic of China. *See Boltless Steel Shelving Units Prepackaged for Sale From the People's Republic of China: Antidumping Duty Order,* 80 FR 63,741 (October 21, 2017); *Boltless Steel Shelving Units Prepackaged for Sale From the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 63,745 (October 21, 2017).

Also excluded from the scope of this investigation are bulk-packed parts or components of boltless steel shelving units that were specifically excluded from the scope of the Boltless Steel Shelving Orders because such bulk-packed parts or components do not contain the steel vertical supports (*i.e.,* uprights and posts) and steel horizontal supports (*i.e.,* beams, braces) packaged together for assembly into a completed boltless steel shelving unit.

Such excluded components of boltless steel shelving are defined as:

(1) Boltless horizontal supports (beams, braces) that have each of the following characteristics: (a) A length of 95 inches or less, (b) made from steel that has a thickness of 0.068 inches or less, and (c) a weight capacity that does not exceed 2500 lbs per pair of beams for beams that are 78'' or shorter, a weight capacity that does not exceed 2200 lbs per pair of beams for beams that are over 78'' long but not longer than 90'', and/or a weight capacity that does not exceed 1800 lbs per pair of beams for beams that are longer than 90'';

(2) shelf supports that mate with the aforementioned horizontal supports; and

(3) boltless vertical supports (upright welded frames and posts) that have each of the following characteristics: (a) A length of 95 inches or less, (b) with no face that exceeds 2.90 inches wide, and (c) made from steel that has a thickness of 0.065 inches or less.

Excluded from the scope of this investigation are: (1) Wall-mounted shelving and racks, defined as shelving and racks that suspend all of the load from the wall, and do not stand on, or transfer load to, the floor; (2) ceiling-mounted shelving and racks, defined as shelving and racks that suspend all of the load from the ceiling and do not stand on, or transfer load to, the floor; and (3) wall/ceiling mounted shelving and racks, defined as shelving and racks that suspend the load from the ceiling and the wall and do not stand on, or transfer load to, the floor. The addition of a wall or ceiling bracket or other device to attach otherwise subject merchandise to a wall or ceiling does not meet the terms of this exclusion.

Also excluded from the scope of this investigation is scaffolding that complies with ANSI/ASSE A10.8—2011—Scaffolding Safety Requirements, CAN/CSA S269.2–M87 (Reaffirmed 2003)—Access Scaffolding for Construction Purposes, and/or Occupational Safety and Health Administration regulations at 29 CFR part 1926 subpart L—Scaffolds.

Also excluded from the scope of this investigation are tubular racks such as garment racks and drying racks, *i.e.,* racks in which the load bearing vertical and horizontal steel members consist solely of: (1) Round tubes that are no more than two inches in diameter; (2) round rods that are no more than two inches in diameter; (3) other tubular shapes that have both an overall height of no more than two inches and an overall width of no more than two inches; and/or (4) wire.

Also excluded from the scope of this investigation are portable tier racks. Portable tier racks must meet each of the following criteria to qualify for this exclusion:

(1) They are freestanding, portable assemblies with a fully welded base and four freely inserted and easily removable corner posts;

(2) They are assembled without the use of bolts, braces, anchors, brackets, clips, attachments, or connectors;

(3) One assembly may be stacked on top of another without applying any additional load to the product being stored on each assembly, but individual portable tier racks are not securely attached to one another to provide interaction or interdependence; and

(4) The assemblies have no mechanism (*e.g.,* a welded foot plate with bolt holes) for anchoring the assembly to the ground.

Also excluded from the scope of this investigation are accessories that are independently bolted to the floor and not attached to the rack system itself, *i.e.,* column protectors, corner guards, bollards, and end row and end of aisle protectors.

Merchandise covered by this investigation is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under the following subheadings: 7326.90.8688, 9403.20.0080, and 9403.90.8041. Subject merchandise may also enter under subheadings 7308.90.3000, 7308.90.6000, 7308.90.9590, and 9403.20.0090. The HTSUS subheadings are provided for convenience and U.S. Customs purposes only. The written description of the scope is dispositive.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Postponement of Final Determination and Extension of Provisional Measures
V. Scope Comments
VI. Scope of the Investigation
VII. Selection of Respondents
VIII. Discussion of the Methodology
A. Non-Market Economy Country
B. Surrogate Country and Surrogate Value Comments
C. Separate Rates
D. Dumping Margin for the Separate Rate Companies Not Individually Examined
E. Combination Rates
F. The China-Wide Entity
G. Application of Facts Available and Adverse Inferences
H. Date of Sale
I. Fair Value Comparisons
J. Export Price
K. Normal Value
L. Factor Valuation Methodology
IX. Currency Conversion
X. Adjustment Under Section 777A(f) of the Act
XI. Adjustment for Countervailable Export Subsidies
XII. Verification
XIII. Conclusion

[FR Doc. 2019–03820 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–864, A–201–850, A–570–102]

Certain Fabricated Structural Steel From Canada, Mexico, and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable February 25, 2019.

FOR FURTHER INFORMATION CONTACT: David Goldberger at (202) 482–4136 (Canada); Alice Maldonado at (202) 482–4682 (the People's Republic of China (China)); and Jeffrey Pedersen at (202) 482–2769 (Mexico); AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On February 4, 2019, the U.S. Department of Commerce (Commerce) received antidumping duty (AD) Petitions concerning imports of certain fabricated structural steel (fabricated structural steel) from Canada, China, and Mexico, which were subsequently amended on February 21, 2019.[1] The Petitions, as amended, were filed in proper form by a subgroup of the American Institute of Steel Construction, LLC, a trade association representing domestic producers of fabricated structural steel. Specifically, the petitioner is the American Institute of Steel Construction Full Member Subgroup (the petitioner). The AD Petitions were accompanied by countervailing duty (CVD) Petitions concerning imports of fabricated structural steel from Canada, China, and Mexico.

On February 7, 2019, Commerce requested supplemental information pertaining to certain aspects of the Petitions in separate supplemental

[1] *See* the petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China,'' dated February 4, 2019, as amended on February 21, 2019 (the Petitions).

questionnaires.[2] Responses to the supplemental questionnaires were filed on February 11 and 12, 2019.[3]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that imports of fabricated structural steel from Canada, China, and Mexico are being, or are likely to be, sold in the United States at less than fair value (LTFV) within the meaning of section 731 of the Act, and that such imports are materially injuring, or threatening material injury to, the domestic industry producing fabricated structural steel in the United States. Consistent with section 732(b)(1) of the Act, the Petitions are accompanied by information reasonably available to the petitioner supporting its allegations.

Section 771(9)(E) of the Act states that ''a trade or business association'' is an interested party if ''a majority'' of its ''members manufacture, produce, or wholesale a domestic like product in the United States. Based on information contained in the petitioner's amended Petition submission of February 21, 2019,[4] as well as its prior submissions pertaining to the membership of the American Institute of Steel Construction, LLC,[5] Commerce finds that the petitioner satisfactorily showed that a majority of its members manufacture, produce, or wholesale a domestic like product in the United States, and therefore the Petitions, as amended, have been filed on behalf of the domestic industry. Commerce also finds that the petitioner demonstrated sufficient industry support with respect to the initiation of the requested AD investigations.[6]

Periods of Investigation

Because the Petitions were filed on February 4, 2019, and amended on February 21, 2019, pursuant to 19 CFR 351.204(b)(1), the period of investigation (POI) for the Canada and Mexico investigations is January 1, 2018, through December 31, 2018. Because China is a non-market economy (NME) country, pursuant to 19 CFR 351.204(b)(1), the POI for the China investigation is July 1, 2018, through December 31, 2018.

Scope of the Investigations

The product covered by these investigations is fabricated structural steel from Canada, China, and Mexico. For a full description of the scope of these investigations, *see* the Appendix to this notice.

Scope Comments

During our review of the Petitions, Commerce contacted the petitioner regarding the proposed scope language to ensure that the scope language in the Petitions is an accurate reflection of the products for which the domestic industry is seeking relief.[7] As a result, the scope of the Petitions was modified to clarify the description of merchandise covered by the Petitions. The description of the merchandise covered by these initiations, as described in the Appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope), including potential overlap with existing orders.[8] To the extent that the scope of any of these investigations overlaps with existing AD/CVD orders, any products covered by that overlap will be excluded from the scope of the relevant investigation. Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information,[9] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit scope comments by 5:00 p.m. Eastern Time (ET) on March 18, 2019, which is the next business day after 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on March 28, 2019, which is 10 calendar days from the initial comments deadline.[10]

Commerce requests that any factual information parties consider relevant to the scope of the investigations be submitted during this period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact Commerce and request permission to submit the additional information. All such submissions must be filed on the records of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).[11]

[2] *See* Commerce Letters, ''Re: Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Fabricated Structural Steel from Canada, the People's Republic of China, and Mexico: Supplemental Questions;'' ''Re: Petition for the Imposition of Antidumping Duties on Imports of Certain Fabricated Structural Steel from Canada: Supplemental Questions;'' ''Re: Petition for the Imposition of Antidumping Duties on Imports of Certain Fabricated Structural Steel from Mexico: Supplemental Questions;'' and ''Re: Petition for the Imposition of Antidumping Duties on Imports of Certain Fabricated Structural Steel from the People's Republic of China: Supplemental Questions.'' All of these documents are dated February 7, 2019.

[3] *See* the petitioner's Letters, ''Re: Certain Fabricated Structural Steel from Canada: Responses to Supplemental Questions on Canada AD Volume III of the Petition'' (Canada AD Supplement); ''Re: Certain Fabricated Structural Steel from Mexico: Response to Supplemental Questions on Mexico AD Volume III of the Petition'' (Mexico AD Supplement); and ''Re: Certain Fabricated Structural Steel from the People's Republic of China: Responses to Supplemental Questions on China AD Volume IV of the Petition'' (China AD Supplement). All of these documents are dated February 11, 2019; *see also* Petitioner's Letter, ''Re: Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China: Responses to Supplemental Questions on General and Injury Volume I of the Petition,'' dated February 12, 2019 (General Issues Supplement).

[4] *See* the petitioner's Letter, ''Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China: Amendment to Petition to Clarify Petitioner,'' dated February 21, 2019 (Amendment to the Petitions) at 2.

[5] *See* the petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China,'' dated February 4, 2019 at Exhibit I–2.

[6] *See* ''Antidumping Duty Investigation Initiation Checklist: Certain Fabricated Structural Steel from Canada (Canada AD Initiation Checklist); Antidumping Duty Investigation Initiation Checklist: Certain Fabricated Structural Steel from the People's Republic of China (China AD Initiation Checklist); and Antidumping Duty Investigation Initiation Checklist: Certain Fabricated Structural Steel from Mexico (Mexico AD Initiation Checklist). These checklists are dated concurrently with, and hereby adopted by, this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[7] *See* Memorandum, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Fabricated Structural Steel from Canada, the People's Republic of China, and Mexico: Phone Call with Counsel to the Petitioner,'' dated February 21, 2019; *see also* the petitioner's Letter, ''Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China: Revision to Scope,'' dated February 22, 2019.

[8] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[9] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[10] *See* 19 CFR 351.303(b).

[11] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/*

Continued

An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Comments on Product Characteristics for AD Questionnaires

Commerce is providing interested parties an opportunity to comment on the appropriate physical characteristics of fabricated structural steel to be reported in response to Commerce's AD questionnaires. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant factors of production (FOPs) accurately, as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics, and (2) product comparison criteria. We note that it is not always appropriate to use all product characteristics as product comparison criteria. We base product comparison criteria on meaningful commercial differences among products. In other words, although there may be some physical product characteristics utilized by manufacturers to describe fabricated structural steel, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, Commerce attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, all product characteristics comments must be filed by 5:00 p.m. ET on March 18, 2019, which is the next business day after 20 calendar days from the signature date of this notice.[12] Any rebuttal comments must be filed by 5:00 p.m. ET on March 25, 2019. All comments and submissions to Commerce must be filed electronically using ACCESS, as explained above, on the record of each of the AD investigations.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,[13] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[14]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the Petitions.[15] Based on our analysis of the information submitted on the record, we have determined that fabricated structural steel, as defined in the scope, constitutes a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[16]

In determining whether the petitioner has standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of the Investigations,'' in the Appendix to this notice. To establish industry support, the petitioner provided its own production of the domestic like product in 2017.[17] The petitioner estimated the production of the domestic like product for the entire domestic industry based on shipment data, because production data for the entire domestic industry are not available, and shipments are a close approximation of production in the fabricated structural steel industry.[18] The petitioner compared its production to the estimated total production of the domestic like product for the entire domestic industry.[19] We relied on data provided by the petitioner for purposes of measuring industry support.[20]

Handbook%20on%20Electronic%20 Filling%20Procedures.pdf.

[12] *See* 19 CFR 351.303(b).

[13] *See* section 771(10) of the Act.

[14] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[15] *See* Volume I of the Petitions, at 14–16 and Exhibit I–5; *see also* General Issues Supplement, at 1–3.

[16] For a discussion of the domestic like product analysis as applied to these cases and information regarding industry support, *see* Canada AD Initiation Checklist, at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Certain Fabricated Structural Steel from Canada, the People's Republic of China, and Mexico (Attachment II); China AD Initiation Checklist at Attachment II; and Mexico AD Initiation Checklist at Attachment II.

[17] *See* Volume I of the Petitions, at 2–3 and Exhibit I–4.

[18] *Id.* at 2–3 and Exhibits I–3 and I–4; *see also* General Issues Supplement, at 3–6.

[19] *See* Volume I of the Petitions, at 2–3.

[20] *Id.* at 2–3 and Exhibit I–3 and I–4; *see also* General Issues Supplement, at 3–6. For further discussion, *see* Canada AD Initiation Checklist, at Attachment II; China AD Initiation Checklist, at

On February 12 and February 13, 2019, we received comments on industry support from Canada, the provincial government of Québec, and Mexico, respectively.[21] The petitioner responded to the Canada's and Mexico's comments on February 19, 2019.[22]

On February 19, 2019, we received comments on industry support from Corey, S.A. de C.V. (Corey), a Mexican producer and exporter of fabricated structural steel.[23]

The petitioner responded to the comments from Corey on February 21, 2019.[24] In addition, the petitioner subsequently clarified and amended the Petitions on February 21, 2019, in response to the comments from Canada, Mexico, and Corey.[25] During consultations held with respect to the Canada and Mexico CVD petitions, Canada and Mexico discussed industry support comments and provided additional comments in the respective CVD consultation papers.[26] On February 22, 2019, we received additional comments on industry support from Canada, Québec, and Mexico.[27] The petitioner responded to Canada's, Québec's, and Mexico's comments on February 25, 2019.[28] For further discussion of these comments, *see* the country-specific AD initiation checklists, at Attachment II.

Our review of the data provided in the Petitions, the General Issues Supplement, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petitions.[29] First, the Petitions established support from domestic producers (or workers) accounting for more than 50 percent of the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[30] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petitions account for at least 25 percent of the total production of the domestic like product.[31] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions.[32] Accordingly, Commerce determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.

Allegations and Evidence of Material Injury and Causation

The petitioner alleges that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at LTFV. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[33]

The petitioner contends that the industry's injured condition is illustrated by the significant volume and increasing market share of subject imports; reduced market share of the U.S. industry; underselling and price depression or suppression; declines in production, shipments, and capacity utilization; negative impact on employment variables; decline in the domestic industry's financial performance; and lost sales and revenues.[34] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, negligibility, as well as cumulation, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[35]

Allegations of Sales at LTFV

The following is a description of the allegation of sales at LTFV upon which Commerce based its decision to initiate AD investigations of imports of fabricated structural steel from Canada, China, and Mexico. The sources of data for the deductions and adjustments relating to U.S. price and normal value (NV) are discussed in greater detail in the AD Initiation Checklist for each country.

Export Price

For China and Mexico, the petitioner based export price (EP) on pricing information for fabricated structural steel produced in, and exported from, those countries and sold or offered for sale in the United States.[36] For China, the petitioner deducted from U.S. price foreign inland freight, foreign brokerage and handling, ocean freight and insurance, and U.S. port expenses.[37] For

Attachment II; and Mexico AD Initiation Checklist, at Attachment II.

[21] *See* Letter from the Government of Canada, the Government of Québec, and Export Development Canada, ''Fabricated Structural Steel from Canada (A–122–864 and C–122–865)—Request for Postponement of Initiation and Disclosure of Members of Petitioner American Institute of Steel Construction and Identities of Known Domestic Producers,'' dated February 12, 2019 (Canada Letter); *see also* Letter from the Government of Mexico, ''Fabricated Structural Steel from Mexico (A–201–850 and C–201–851)—Request to Dismiss Petitions or Otherwise Postpone Initiation,'' dated February 13, 2019 (Mexico Letter).

[22] *See* the petitioner's Letter, ''Certain Fabricated Structural Steel from Canada and Mexico: Response to Respondents' Request to Reject Petitions or Postpone Initiation,'' dated February 19, 2019.

[23] *See* Letter from Corey, ''Fabricated Structural Steel from Mexico: Standing Challenge—Request to Decline Initiation of Antidumping and Countervailing Duty Investigations,'' dated February 19, 2019.

[24] *See* the petitioner's Letter, ''Certain Fabricated Structural Steel from Canada and Mexico: Response to Respondents' Standing Challenge and Request to Decline Initiation,'' dated February 21, 2019.

[25] *See* Amendment to the Petitions.

[26] *See* Ex-Parte Memorandum, ''Meeting with Officials from the Government of Mexico on the Countervailing Duty Petition on Certain Fabricated Structural Steel from Mexico'' dated February 19, 2019; *see also* Memorandum, ''Countervailing Duty Petition on Certain Fabricated Structural Steel from Canada: GOC Consultations,'' dated February 21, 2019; *see also* Letter from Mexico, ''Fabricated Structural Steel from Mexico (C–201–851)—Submission of Consultations Paper,'' dated February 20, 2019; *see also* Letter from Canada, ''Fabricated Structural Steel from Canada (A–122–864 and C–122–865)—Consultations Paper.

[27] *See* Letter from Québec, ''Fabricated Structural Steel from Canada, (A–122–864 and C–122–865): Response to AISC Amendment to Petition,'' dated February 22, 2019; *see also* Letter from Canada, ''Fabricated Structural Steel from Canada (A–122–864 and C–122–865)—Response to AISC Amendment to Petition,'' dated February 22, 2019; *see also* Letter from Mexico, ''Fabricated Structural Steel from Mexico (C–201–851, A–201–850)—Comments on Change of Petitioner,'' dated February 22, 2019.

[28] *See* Letter from the petitioner, ''Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China,'' dated February 25, 2019.

[29] *See* Canada AD Initiation Checklist, at Attachment II; China AD Initiation Checklist, at Attachment II; and Mexico AD Initiation Checklist, at Attachment II.

[30] *See* section 732(c)(4)(D) of the Act; *see also* Canada AD Initiation Checklist, at Attachment II; China AD Initiation Checklist, at Attachment II; and Mexico AD Initiation Checklist, at Attachment II.

[31] *See* Canada AD Initiation Checklist, at Attachment II; China AD Initiation Checklist, at Attachment II; and Mexico AD Initiation Checklist, at Attachment II.

[32] *Id.*

[33] *See* Volume I of the Petitions, at 22 and Exhibit I–8.

[34] *Id.* at 11–41 and Exhibits I–3, I–5, I–8, I–10 through I–22; *see also* General Issues Supplement, at 6.

[35] *See* Canada AD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Certain Fabricated Structural Steel from Canada, the People's Republic of China, and Mexico (Attachment III); *see also* China AD Initiation Checklist, at Attachment III; *see also* Mexico AD Initiation Checklist, at Attachment III.

[36] *See* China and Mexico AD Initiation Checklists; *see also See* Volume IV of the Petition, at 3 and Exhibit IV–2.

[37] *See* Volume IV of the Petition at 4; *see also* China AD Supplement, at Exhibit IV—Supp–2.

Mexico, the petitioner deducted from U.S. price foreign inland freight, foreign brokerage and handling, U.S. brokerage and handling, and U.S. inland freight.[38]

Constructed Export Price

For Canada, because the petitioner had reason to believe that the sale was made on a constructed export price (CEP) basis,[39] the petitioner based CEP on pricing information for fabricated structural steel produced in Canada by a Canadian producer and sold or offered for sale in the United States.[40] The petitioner made deductions from U.S. price for foreign inland freight (including foreign inland insurance and foreign brokerage and handling), U.S. inland freight, and U.S. brokerage and handling charges.[41] The petitioner also deducted further manufacturing expenses and CEP profit from U.S. price.[42]

Normal Value

For Canada and Mexico, the petitioner was unable to obtain information relating to the prices charged for fabricated structural steel in Canada and Mexico, or any third country market.[43] The petitioner noted that fabricated structural steel is a specialized product which is sold to specific classes of customers and for special projects and, with few exceptions, no two fabricated structural steel projects are identical.[44] Because home market and third country prices were not reasonably available, the petitioners calculated NV based on constructed value (CV). For further discussion of CV, *see* the section ''Normal Value Based on Constructed Value'' below.[45]

With respect to China, Commerce considers China to be an NME country.[46] In accordance with section 771(18)(C)(i) of the Act, any determination that a foreign country is an NME country shall remain in effect until revoked by Commerce. Therefore, we continue to treat China as an NME country for purposes of the initiation of this investigation. Accordingly, NV in China is appropriately based on factors of production (FOPs) valued in a surrogate market economy country, in accordance with section 773(c) of the Act.[47]

The Petitions claim Brazil is an appropriate surrogate country for China because it is a market economy country that is at a level of economic development comparable to that of China, and it is a significant producer of identical merchandise.[48] The Petitions provided publicly-available information from Brazil to value all FOPs.[49] However, the Petitions relied upon the financial statement of Grupo Carso, S.A.B. de C.V. (Carso), a Mexican producer of fabricated structural steel, to value financial ratios (*i.e.,* manufacturing overhead, selling, general and administrative (SG&A) expenses, and profit) because the petitioner stated that it attempted to locate the financial ratios of a producer of identical or comparable merchandise in Brazil; however, ''many companies within Brazil have reported net losses for their most recent fiscal years or have been required to report 'qualified' financial statements.'' [50] Therefore, based on the information provided by the petitioner, we determine that it is appropriate to use Brazil as the primary surrogate country, but rely on the financial statement of a Mexican producer of fabricated structural steel to value financial ratios, for initiation purposes.

Interested parties will have the opportunity to submit comments regarding surrogate country selection and, pursuant to 19 CFR 351.301(c)(3)(i), will be provided an opportunity to submit publicly available information to value FOPs within 30 days before the scheduled date of the preliminary determination.

Factors of Production

Because information regarding the volume of inputs consumed by the Chinese producer/exporter was not reasonably available, the Petitions used the product-specific consumption rates of a U.S. fabricated structural steel producer as a surrogate to estimate the Chinese manufacturer's FOPs.[51] The Petitions valued the estimated FOPs using surrogate values from Brazil, as noted above.[52] The Petitions used an average exchange rate to convert the data to U.S. dollars, where applicable.[53]

Normal Value Based on Constructed Value

As noted above, because home market and third country prices were not available for Mexico and Canada, the Petitions based NV on CV.[54] Pursuant to section 773(e) of the Act, CV consists of the cost of manufacturing (COM), SG&A expenses, financial expenses, and profit.[55]

For Canada and Mexico, the Petitions calculated the COM based on the input factors of production and usage rates from a U.S. producer of fabricated structural steel. The input factors of production were valued using publicly available data on costs specific to Canada and Mexico during the proposed POI.[56] Specifically, the prices for raw materials (and propane for Canada) were valued using publicly available import and domestic price data for Canada and Mexico.[57] Labor and energy costs were valued using publicly available sources for Canada and Mexico.[58]

For Canada, the Petitions relied on the fiscal year (FY) 2017 audited financial statements of Empire Industries Limited (Empire), a Canadian producer of fabricated structural steel, to determine the per-unit factory overhead costs associated with the production of fabricated structural steel.[59] The Petitions also relied on Empire's FY 2017 audited financial statements to determine the SG&A expense ratio used to calculate the per-unit SG&A expenses and the financial expense ratio [60] used to calculate the per-unit financial expenses.[61] To determine the profit rate, the Petitions relied on Empire's FY 2017 audited financial statements.[62] Because

[38] *See* the Mexico AD Initiation Checklist at 7–8 and Volume IV of the Petition at 5–6.

[39] *See* Canada AD Supplement, at 1. The petitioner requested business proprietary treatment for the information regarding why it believes the offer for sale was made on a CEP basis.

[40] *See* Canada AD Initiation Checklist.

[41] *Id.*

[42] *Id.*

[43] *See* Canada and Mexico AD Initiation Checklists.

[44] *See* Volume II of the Petition, at 11; and Volume III of the Petition, at 9.

[45] In accordance section 773(b)(2) of the Act, for this investigation, Commerce will request information necessary to calculate the CV and cost of production (COP) to determine whether there are reasonable grounds to believe or suspect that sales of the foreign like product have been made at prices that represent less than the COP of the product.

[46] *See Antidumping Duty Investigation of Certain Aluminum Foil from the People's Republic of China: Affirmative Preliminary Determination of Sales at Less-Than-Fair Value and Postponement of Final Determination,* 82 FR 50858, 50861 (November 2, 2017), and accompanying decision memorandum, *China's Status as a Non-Market Economy,* unchanged in *Certain Aluminum Foil from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 83 FR 9282 (March 5, 2018).

[47] *See* China AD Initiation Checklist.

[48] *See* Volume IV of the Petition, at 9–10 and Exhibit IV–11.

[49] *Id.* at 16 and Exhibit IV–17

[50] *Id.* at 18 and Exhibits IV–10 and IV–21.

[51] *Id.* at 11 and Exhibit IV–12.

[52] *Id.* at 16 and Exhibits IV–17; *see also* China AD Supplement at Exhibit IV–Supp–3.

[53] *See* Volume IV of the Petition at 15 and Exhibit IV–16.

[54] *See* Volume II of the Petition at 11; and Volume III of the Petition at 9.

[55] *See* Canada AD Initiation Checklist and Mexico AD Initiation Checklist.

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] *See* Volume II of the Petition at 18 and Exhibit II–22A and Exhibit II–22B.

[60] *See* Canada AD Initiation Checklist.

[61] *Id.*

[62] *Id.*

Empire operated at a loss for FY 2017, the Petitions conservatively did not include an amount for profit in the calculation of CV.

For Mexico, the Petitions calculated factory overhead, SG&A, interest and profit based on the 2017 audited financial statements of Carso, a Mexican producer of fabricated structural steel.[63]

Fair Value Comparisons

Based on the data provided by the Petitions, there is reason to believe that imports of fabricated structural steel from Canada, China, and Mexico are being, or are likely to be, sold in the United States at LTFV. Based on comparisons of EP, or CEP, to NV in accordance with sections 772 and 773 of the Act, the estimated dumping margins for fabricated structural steel for each of the countries covered by this initiation are as follows: (1) Canada—30.41 percent;[64] (2) China—222.35 percent;[65] and (3) Mexico—30.58 percent.[66]

Initiation of LTFV Investigations

Based upon the examination of the Petitions and supplemental responses, we find that the Petitions meet the requirements of section 732 of the Act. Therefore, we are initiating AD investigations to determine whether imports of fabricated structural steel from Canada, China, and Mexico are being, or are likely to be, sold in the United States at LTFV. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Respondent Selection

With respect to Canada and Mexico, the petitioner named 50 companies in Canada[67] and 18 companies in Mexico,[68] as producers/exporters of fabricated structural steel. Following standard practice in AD investigations involving market economy countries, in the event Commerce determines that the number of companies is large and it cannot individually examine each company based upon Commerce's resources, where appropriate, Commerce intends to select respondents in Canada and Mexico based on U.S. Customs and Border Protection (CBP) data for U.S. imports under the appropriate Harmonized Tariff Schedule of the United States (HTSUS) numbers listed with the scope in the Appendix, below.[69]

With respect to China, the petitioners named 220 producers/exporters of fabricated structural steel in China. In AD investigations involving NME countries, Commerce selects respondents based on quantity and value (Q&V) questionnaires in cases where it cannot individually examine each company based upon its resources. After considering the large number of producers and exporters identified in the Petition, and considering the resources that must be used by Commerce to mail Q&V questionnaires to all of these companies, Commerce has determined that we do not have sufficient administrative resources to mail Q&V questionnaires to all 220 identified producers and exporters. Therefore, Commerce has determined to limit the number of Q&V questionnaires it will send out to exporters and producers based on CBP data for imports during the POI under the appropriate HTSUS numbers listed with the scope in the Appendix, below. Accordingly, Commerce will send Q&V questionnaires to the largest producers and exporters that are identified in the CBP data for which there is address information on the record.

On February 25, 2019, Commerce released CBP data on imports of fabricated structural steel from Canada, China, and Mexico under APO to all parties with access to information protected by APO and indicated that interested parties wishing to comment on the CBP data must do so within three business days of the publication date of the notice of initiation of these investigations.[70] We further stated that we will not accept rebuttal comments.

In addition, Commerce will post the Q&V questionnaire along with filing instructions on the Enforcement and Compliance website at *http://www.trade.gov/enforcement/news.asp.* In accordance with our standard practice for respondent selection in AD cases involving NME countries, we intend to base respondent selection on the responses to the Q&V questionnaire that we receive.

Producers/exporters of fabricated structural steel from China that do not receive Q&V questionnaires by mail may still submit a response to the Q&V questionnaire and can obtain a copy of the Q&V questionnaire from Enforcement & Compliance's website. The Q&V response must be submitted by the relevant Chinese exporters/producers no later than 5:00 p.m. ET on March 15, 2019. All Q&V responses must be filed electronically via ACCESS.

Separate Rates

In order to obtain separate-rate status in an NME investigation, exporters and producers must submit a separate-rate application.[71] The specific requirements for submitting a separate-rate application in the China investigation are outlined in detail in the application itself, which is available on Commerce's website at *http://enforcement.trade.gov/nme/nme-sep-rate.html.* The separate-rate application will be due 30 days after publication of this initiation notice.[72] Exporters and producers who submit a separate-rate application and are selected as mandatory respondents will be eligible for consideration for separate-rate status only if they respond to all parts of Commerce's AD questionnaire as mandatory respondents. Commerce requires that companies from China submit a response to both the Q&V questionnaire and the separate-rate application by the respective deadlines in order to receive consideration for separate-rate status. Companies not filing a timely Q&V response will not receive separate-rate consideration.

Use of Combination Rates

Commerce will calculate combination rates for certain respondents that are eligible for a separate rate in an NME investigation. The Separate Rates and Combination Rates Bulletin states:

> {w}hile continuing the practice of assigning separate rates only to exporters, all separate rates that the Department will now assign in its NME Investigation will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the

[63] *See* Mexico AD Initiation Checklist.

[64] *See* Canada AD Initiation Checklist.

[65] *See* China AD Initiation Checklist.

[66] *See* Mexico AD Initiation Checklist.

[67] *See* Volume I of the Petitions, at Exhibit I–7.

[68] *Id.*

[69] *See, e.g., Polyester Textured Yarn from India and the People's Republic of China: Initiation of Less-Than-Fair-Value Investigations,* 83 FR 58223, 58227 (November 19, 2018).

[70] *See* Memoranda, ''Less-Than-Fair-Value Investigation of Certain Fabricated Structural Steel from Canada: Release of U.S. Customs and Border Protection Data;'' ''Less-Than-Fair-Value Investigation of Certain Fabricated Structural Steel from the People's Republic of China: Release of U.S. Customs and Border Protection Data;'' and ''Less-Than-Fair-Value Investigation of Certain Fabricated Structural Steel from Mexico: Release of U.S. Customs and Border Protection Data,'' dated February 25, 2019.

[71] *See* Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigation involving Non-Market Economy Countries (April 5, 2005), available at *http://enforcement.trade.gov/policy/bull05-1.pdf* (Policy Bulletin 05.1).

[72] Although in past investigations this deadline was 60 days, consistent with 19 CFR 351.301(a), which states that ''the Secretary may request any person to submit factual information at any time during a proceeding,'' this deadline is now 30 days.

period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the weighted-average of the individually calculated rates. This practice is referred to as the application of ''combination rates'' because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question and produced by a firm that supplied the exporter during the period of investigation.[73]

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to the governments of Canada, China, and Mexico *via* ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petitions to each exporter named in the Petitions, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of fabricated structural steel from Canada, China, and/or Mexico are materially injuring, or threatening material injury to, a U.S. industry.[74] A negative ITC determination for any country will result in the investigation being terminated with respect to that country.[75] Otherwise, the investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted[76] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[77] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in these investigations.

Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of CV under section 773(e) of the Act.[78] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of a respondent's initial section D questionnaire response.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in a letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these investigations.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[79] Parties must use the certification formats provided in 19 CFR 351.303(g).[80] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 732(c)(2) and 777(i) of the Act, and 19 CFR 351.203(c).

[73] *See* Policy Bulletin 05.1 at 6 (emphasis added).

[74] *See* section 733(a) of the Act.

[75] *Id.*

[76] *See* 19 CFR 351.301(b).

[77] *See* 19 CFR 351.301(b)(2).

[78] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[79] *See* section 782(b) of the Act.

[80] *See also Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*). Answers to frequently asked questions regarding the *Final Rule* are available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

Dated: February 25, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—Scope of the Investigations

The merchandise covered by these investigations is carbon and alloy fabricated structural steel. Fabricated structural steel is made from steel in which: (1) Iron predominates, by weight, over each of the other contained elements; and (2) the carbon content is two percent or less by weight. Fabricated structural steel products are steel products that have been fabricated for erection or assembly into structures, including, but not limited to, buildings (commercial, office, institutional, and multi-family residential); industrial and utility projects; parking decks; arenas and convention centers; medical facilities; and ports, transportation and infrastructure facilities. Fabricated structural steel is manufactured from carbon and alloy (including stainless) steel products such as angles, columns, beams, girders, plates, flange shapes (including manufactured structural shapes utilizing welded plates as a substitute for rolled wide flange sections), channels, hollow structural section (HSS) shapes, base plates, and plate-work components. Fabrication includes, but is not limited to cutting, drilling, welding, joining, bolting, bending, punching, pressure fitting, molding, grooving, adhesion, beveling, and riveting and may include items such as fasteners, nuts, bolts, rivets, screws, hinges, or joints.

The inclusion, attachment, joining, or assembly of non-steel components with fabricated structural steel does not remove the fabricated structural steel from the scope.

Fabricated structural steel is covered by the scope of the investigations regardless of whether it is painted, varnished, or coated with plastics or other metallic or non-metallic substances and regardless of whether it is assembled or partially assembled, such as into modules, modularized construction units, or sub-assemblies of fabricated structural steel.

Subject merchandise includes fabricated structural steel that has been assembled or further processed in the subject country or a third country, including but not limited to painting, varnishing, trimming, cutting, drilling, welding, joining, bolting, punching, bending, beveling, riveting, galvanizing, coating, and/or slitting or any other processing that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the fabricated structural steel.

Specifically excluded from the scope of these investigations are:

1. Fabricated steel concrete reinforcing bar (rebar) if: (i) It is a unitary piece of fabricated rebar, not joined, welded, or otherwise connected with any other steel product or part; or (ii) it is joined, welded, or otherwise connected only to other rebar.

2. Fabricated structural steel for bridges and bridge sections that meets American Association of State and Highway and Transportation Officials (AASHTO) bridge construction requirements or any state or local derivatives of the AASHTO bridge construction requirements.

3. Pre-engineered metal building systems, which are defined as complete metal buildings that integrate steel framing, roofing and walls to form one, pre-engineered building system, that meet Metal Building Manufacturers Association guide specifications. Pre-engineered metal building systems are typically limited in height to no more than 60 feet or two stories.

4. Steel roof and floor decking systems that meet Steel Deck Institute standards.

5. Open web steel bar joists and joist girders that meet Steel Joist Institute specifications.

The products subject to the investigations are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings: 7308.90.3000, 7308.90.6000, and 7308.90.9590.

The products subject to the investigations may also enter under the following HTSUS subheadings: 7216.91.0010, 7216.91.0090, 7216.99.0010, 7216.99.0090, 7222.40.6000, 7228.70.6000, 7301.10.0000, 7301.20.1000, 7301.20.5000, 7308.40.0000, 7308.90.9530, and 9406.90.0030.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the investigations is dispositive.

[FR Doc. 2019–03818 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–879]

Polyvinyl Alcohol From the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is initiating a changed circumstances review and preliminarily determining that Sinopec Chongqing SVW Chemical Co., Ltd. (SVW) is the successor-in-interest to Sinopec Sichuan Vinylon Works (Sichuan SVW) for the purposes of the antidumping duty order on polyvinyl alcohol (PVA) from the People's Republic of China (China).

DATES: Applicable March 4, 2019.

FOR FURTHER INFORMATION CONTACT: Charles Doss, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–4474.

SUPPLEMENTARY INFORMATION:

Background

On October 1, 2003, Commerce published in the **Federal Register** an antidumping duty order on PVA from China.[1] On December 7, 2018, SVW, a foreign producer and exporter of polyvinyl alcohol from China, and Wego Chemical and Mineral Corp. (Wego), an importer of polyvinyl alcohol from China (collectively, SVW and Wego) requested that, pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.216(b), Commerce conduct an expedited changed circumstances review of the *Order* to confirm that SVW is the successor-in-interest to Sichuan SVW and, accordingly, to assign SVW the cash deposit rate of Sichuan SVW.[2] In its submission, SVW and Wego explain that Sinopec Sichuan Vinylon Works (*i.e.,* Sichuan SVW) has changed its name to Sinopec Chongqing SVW Chemical Co., Ltd. (*i.e.,* SVW), and aver that no substantive changes other than this change of name have otherwise occurred.[3] SVW and Wego further requested that Commerce combine the notice of initiation and preliminary results pursuant to 19 CFR 351.221(c)(3)(ii) and (iii).[4] We did not receive comments from other interested parties concerning this request.

Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[5] Accordingly, the revised deadline for issuance of this initiation and the preliminary results of changed circumstances review is now March 5, 2019.

Scope of the *Order*

The merchandise covered by the order is PVA. This product consists of all PVA hydrolyzed in excess of 80 percent, whether or not mixed or diluted with commercial levels of defoamer or boric acid, except as noted below.

---

[1] *See Antidumping Duty Order: Polyvinyl Alcohol from the People's Republic of China,* 68 FR 56620 (October 1, 2003) (the *Order*).

[2] *See* SVW and Wego's letter, ''Polyvinyl Alcohol from China: Request for Changed Circumstances Review,'' dated December 12, 2018 (CCR Request).

[3] *Id.* at 1–4.

[4] *Id.* at 2.

[5] *See* Memorandum to the Record from Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

The following products are specifically excluded from the scope of this order:

(1) PVA in fiber form.

(2) PVA with hydrolysis less than 83 mole percent and certified not for use in the production of textiles.

(3) PVA with hydrolysis greater than 85 percent and viscosity greater than or equal to 90 cps.

(4) PVA with a hydrolysis greater than 85 percent, viscosity greater than or equal to 80 cps but less than 90 cps, certified for use in an ink jet application.

(5) PVA for use in the manufacture of an excipient or as an excipient in the manufacture of film coating systems which are components of a drug or dietary supplement, and accompanied by an end-use certification.

(6) PVA covalently bonded with cationic monomer uniformly present on all polymer chains in a concentration equal to or greater than one mole percent.

(7) PVA covalently bonded with carboxylic acid uniformly present on all polymer chains in a concentration equal to or greater than two mole percent, certified for use in a paper application.

(8) PVA covalently bonded with thiol uniformly present on all polymer chains, certified for use in emulsion polymerization of non-vinyl acetic material.

(9) PVA covalently bonded with paraffin uniformly present on all polymer chains in a concentration equal to or greater than one mole percent.

(10) PVA covalently bonded with silan uniformly present on all polymer chains certified for use in paper coating applications.

(11) PVA covalently bonded with sulfonic acid uniformly present on all polymer chains in a concentration level equal to or greater than one mole percent.

(12) PVA covalently bonded with acetoacetylate uniformly present on all polymer chains in a concentration level equal to or greater than one mole percent.

(13) PVA covalently bonded with polyethylene oxide uniformly present on all polymer chains in a concentration level equal to or greater than one mole percent.

(14) PVA covalently bonded with quaternary amine uniformly present on all polymer chains in a concentration level equal to or greater than one mole percent.

(15) PVA covalently bonded with diacetoneacrylamide uniformly present on all polymer chains in a concentration level greater than three mole percent, certified for use in a paper application.

The merchandise subject to this order is currently classifiable under subheading 3905.30.00 of the *Harmonized Tariff Schedule of the United States* (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Initiation and Preliminary Results

Pursuant to section 751(b)(1) of the Act, Commerce will conduct a changed circumstances review upon receipt of information concerning, or a request from, an interested party for a review of an antidumping duty order which shows changed circumstances sufficient to warrant a review of the order. In the past, Commerce has used changed circumstances reviews to address the applicability of cash deposit rates after there have been changes in the name or structure of a respondent, such as a merger or spinoff ('successor-in-interest' or 'successorship' determinations).[6] Based on the request from SVW and Wego, and in accordance with section 751(b)(1) of the Act and 19 CFR 351.216(d) and (e), we are initiating a changed circumstances review to determine whether SVW is the successor-in-interest to Sichuan SVW for purposes of antidumping duty liability.

Section 351.221(c)(3)(ii) of Commerce's regulations permits Commerce to combine the notice of initiation of a changed circumstances review and the notice of preliminary results if Commerce concludes that expedited action is warranted.[7] In this instance, because the record contains information necessary to make a preliminary finding, we find that expedited action is warranted and have combined the notice of initiation and the notice of preliminary results.[8]

Accordingly, pursuant to section 751(b) of the Act, we have conducted a successor-in-interest analysis in response to SWV and Wego's request. In making a successor-in-interest determination, Commerce examines several factors, including, but not limited to, changes in the following: (1) Management; (2) production facilities; (3) supplier relationships; and (4) customer base.[9] While no single factor or combination of factors will necessarily provide a dispositive indication of a successor-in-interest relationship, generally, Commerce will consider the new company to be the successor to the previous company if the new company's resulting operation is not materially dissimilar to that of its predecessor.[10] Thus, if the evidence demonstrates that, with respect to the production and sales of the subject merchandise, the new company operates as essentially the same business entity as the former company, Commerce will accord the new company the same antidumping treatment as its predecessor.[11]

In their request, SVW and Wego supplied evidence for Commerce to determine preliminarily that SVW is the successor-in-interest of Sichuan SVW. SVW and Wego provided documentation of approval of SVW's name change from regulators [12] and its business license before and after the change.[13] In addition, the record includes lists of SVW's management before and after the name change,[14] supporting SVW and Wego's assertion that the management is identical.[15]

Further, SVW and Wego provided an announcement of SVW's name change, articles of association, and business licenses that specify that its business premises are the same,[16] and support the claim that SVW's production facilities, operations, and scope of business have not materially changed as a result of the name change.[17] Moreover, SVW and Wego provide sufficient

[6] *See, e.g., Diamond Sawblades and Parts Thereof from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 82 FR 51605, 51606 (November 7, 2017) (*Diamond Sawblades Preliminary*), unchanged in *Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review,* 82 FR 60177 (December 19, 2017) (*Diamond Sawblades Final*).

[7] *See* 19 CFR 351.221(c)(3)(ii). *See also Certain Pasta from Italy: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 80 FR 33480, 33480–41 (June 12, 2015) (*Pasta from Italy Preliminary Results*) (unchanged in *Certain Pasta from Italy: Final Results of Changed Circumstances Review,* 80 FR 48807 (August 14, 2015) (*Pasta from Italy Final Results*).

[8] *See, e.g., Pasta from Italy Preliminary Results,* 80 FR at 33480–41 (unchanged in *Pasta from Italy Final Results,* 80 FR at 48807).

[9] *See, e.g., Diamond Sawblades Final* and *Certain Frozen Warmwater Shrimp from India: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review,* 83 FR 37784 (August 2, 2018) (unchanged in *Certain Frozen Warmwater Shrimp from India: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 83 FR 49909 (October 3, 2018)).

[10] *Id.*

[11] *Id. See also, e.g., Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 64953 (October 24, 2012), unchanged in *Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 73619 (December 11, 2012).

[12] *See* SVW CCR Request at Attachment 1.

[13] *Id.* at Attachment 5.

[14] *Id.* at Attachment 3.

[15] *Id.* at 3.

[16] *Id.* at Attachment 2.

[17] *Id.* at Attachment 3.

information to support their assertion that there have been no material changes to SVW's raw material suppliers and only minor changes to its customer base before and following its name change.[18]

Based on the aforementioned evidence on the record, we preliminarily determine that SVW is the successor-in-interest to Sichuan SVW, as the change in the business' name was not accompanied by significant changes to its management and operations, production facilities, supplier relationships, or customer base. Thus, we preliminarily determine that SVW operates as essentially the same business entity as Sichuan SVW, that SVW is the successor-in-interest to Sichuan SVW, and that SVW should receive the same antidumping duty cash deposit rate with respect to subject merchandise as its predecessor.

Public Comment

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of publication of this notice. In accordance with 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the case briefs, in accordance with 19 CFR 351.309(d). Parties who submit case or rebuttal briefs are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[19] All comments are to be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), available to registered users at *https://access.trade.gov* and in the Central Records Unit, Room B8024, of the main Department of Commerce building, and must also be served on interested parties. An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the day it is due.[20]

Consistent with 19 CFR 351.216(e), we will issue the final results of this changed circumstances review no later than 270 days after the date on which this review was initiated, or within 45 days if all parties agree to our preliminary finding. This notice is published in accordance with sections 751(b)(1) and 777(i) of the Act and 19 CFR 351.216(b), 351.221(b) and 351.221(c)(3).

Dated: February 26, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–03821 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–DS–P

[18] *Id.*

[19] *See* 19 CFR 351.309(c)(2).

[20] *See* 19 CFR 351.303(b).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–122–865, C–201–851, C–570–103]

Certain Fabricated Structural Steel From Canada, Mexico, and the People's Republic of China: Initiation of Countervailing Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable February 25, 2019.

FOR FURTHER INFORMATION CONTACT: Whitley Herndon at (202) 482–6274 (Canada), Thomas Martin (202) 482–3936 or Trisha Tran at (202) 482–4852 (Mexico), or Darla Brown at (202) 482–1791 (People's Republic of China (China)), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On February 4, 2019, the U.S. Department of Commerce (Commerce) received countervailing duty (CVD) Petitions concerning imports of certain fabricated structural steel (fabricated structural steel) from Canada, Mexico, and China, which were subsequently amended on February 21, 2019.[1] The Petitions, as amended, were filed in proper form by a subgroup of the American Institute of Steel Construction, LLC, a trade association representing domestic producers of fabricated structural steel. Specifically, the petitioner is the American Institute of Steel Construction Full Member Subgroup (the petitioner). The CVD Petitions were accompanied by antidumping duty (AD) Petitions concerning imports of fabricated structural steel from Canada, Mexico, and China.

During the period February 7 through February 14, 2019, Commerce requested supplemental information pertaining to certain aspects of the Petitions in separate supplemental questionnaires.[2] Responses to the supplemental questionnaires were filed between February 12 and February 19, 2019.[3]

In accordance with section 702(b)(1) of the Tariff Act of 1930, as amended (the Act), the petitioner alleges that the Governments of Canada, Mexico, and China, as well as the Canadian provincial governments of Alberta, British Colombia (BC), Manitoba, New Brunswick, Ontario, Québec, Prince Edward Island (PEI) and Saskatchewan, are providing countervailable subsidies, within the meaning of sections 701 and 771(5) of the Act, to producers of fabricated structural steel in Canada, Mexico, and China and that imports of such products are materially injuring, or threatening material injury to, the domestic industry producing fabricated structural steel in the United States. Consistent with section 702(b)(1) of the Act and 19 CFR 351.202(b), for those alleged programs on which we are initiating CVD investigations, the Petitions are accompanied by information reasonably available to the petitioner supporting their allegations.

[1] *See* the petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China,'' dated February 4, 2019, as amended on February 21, 2019 (the Petitions).

[2] *See* Commerce Letters, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Fabricated Structural Steel from Canada, the People's Republic of China, and Mexico: Supplemental Questions,'' dated February 7, 2019, ''Petition for the Imposition of Countervailing Duties on Imports of Certain Fabricated Structural Steel from the People's Republic of China (China): Supplemental Questions,'' dated February 7, 2019, ''Petition for the Imposition of Countervailing Duties on Certain Fabricated Structural Steel from Canada: Supplemental Questions,'' dated February 8, 2019, ''Petition for the Imposition of Countervailing Duties on Certain Fabricated Structural Steel from Mexico: Supplemental Questions,'' dated February 8, 2019, and ''Petition for the Imposition of Countervailing Duties on Imports of Certain Fabricated Structural Steel from Mexico: Additional Supplemental Questions,'' dated February 14, 2019.

[3] *See* the petitioner's Letters, ''Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China: Responses to Supplemental Questions on General and Injury Volume I of the Petition,'' dated February 12, 2019 (General Issues Supplement), ''Certain Fabricated Structural Steel from Canada: Responses to Supplemental Questions on Canada CVD Volume V of the Petition,'' dated February 12, 2019, ''Certain Fabricated Structural Steel from Canada: Responses to Supplemental Questions on Mexico CVD Volume VI of the Petition,'' dated February 12, 2019, ''Certain Fabricated Structural Steel from the People's Republic of China: Responses to Supplemental Questions on China CVD Volume VII of the Petition,'' dated February 12, 2019, and ''Certain Fabricated Structural Steel from Mexico: Responses to Second Supplemental Questions in CVD Volume VI of the Petition,'' dated February 19, 2019.

Section 771(9)(E) of the Act states that ''a trade or business association'' is an interested party if ''a majority'' of its ''members manufacture, produce, or wholesale a domestic like product in the United States. Based on information contained in the petitioner's amended Petition submission of February 21, 2019,[4] as well as its prior submissions pertaining to the membership of the American Institute of Steel Construction, LLC,[5] Commerce finds that the petitioner satisfactorily showed that a majority of its members manufacture, produce, or wholesale a domestic like product in the United States, and therefore the Petitions, as amended, have been filed on behalf of the domestic industry. Commerce also finds that the petitioner demonstrated sufficient industry support with respect to the initiation of the requested CVD investigations.[6]

Period of Investigations

Because the Petitions were filed on February 4, 2019, and amended on February 21, 2019, the period of investigation for each investigation is January 1, 2018, through December 31, 2018.

Scope of the Investigations

The product covered by these investigations is fabricated structural steel from Canada, Mexico, and China. For a full description of the scope of these investigations, *see* the Appendix to this notice.

Scope Comments

During our review of the Petitions, Commerce contacted the petitioner regarding the proposed scope language to ensure that the scope language in the Petitions is an accurate reflection of the products for which the domestic industry is seeking relief.[7] As a result, the scope of the Petitions was modified to clarify the description of merchandise covered by the Petitions. The description of the merchandise covered by these initiations, as described in the Appendix to this notice, reflects these clarifications.

As discussed in the *Preamble* to Commerce's regulations, we are setting aside a period for interested parties to raise issues regarding product coverage (scope), including potential overlap with existing orders.[8] To the extent that the scope of any of these investigations overlaps with existing AD/CVD orders, any products covered by that overlap will be excluded from the scope of the relevant investigation. Commerce will consider all comments received from interested parties and, if necessary, will consult with interested parties prior to the issuance of the preliminary determination. If scope comments include factual information,[9] all such factual information should be limited to public information. To facilitate preparation of its questionnaires, Commerce requests that all interested parties submit scope comments by 5:00 p.m. Eastern Time (ET) on March 18, 2019, which is the next business day after 20 calendar days from the signature date of this notice. Any rebuttal comments, which may include factual information, must be filed by 5:00 p.m. ET on March 28, 2019, which is 10 calendar days from the initial comments deadline.[10]

Commerce requests that any factual information parties consider relevant to the scope of the investigations be submitted during this period. However, if a party subsequently finds that additional factual information pertaining to the scope of the investigations may be relevant, the party may contact Commerce and request permission to submit the additional information. All such submissions must be filed on the records of the concurrent AD and CVD investigations.

Filing Requirements

All submissions to Commerce must be filed electronically using Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS).[11] An electronically filed document must be received successfully in its entirety by the time and date it is due. Documents exempted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Enforcement and Compliance's APO/Dockets Unit, Room 18022, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, and stamped with the date and time of receipt by the applicable deadlines.

Consultations

Pursuant to sections 702(b)(4)(A)(i) and (ii) of the Act, Commerce notified representatives of Canada, Mexico, and China of the receipt of the Petitions and provided them the opportunity for consultations with respect to the CVD Petitions.[12] Commerce held consultations with Canada and Mexico, on February 19, 2019.[13] China did not request consultations.

Determination of Industry Support for the Petitions

Section 702(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 702(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the

[4] *See* the petitioner's Letter, ''Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China: Amendment to Petition to Clarify Petitioner,'' dated February 21, 2019 (Amendment to the Petitions) at 2.

[5] *See* the petitioner's Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China,'' dated February 4, 2019 at Exhibit I–2.

[6] *See* ''Countervailing Duty Investigation Initiation Checklist: Certain Fabricated Structural Steel from Canada (Canada CVD Initiation Checklist); Countervailing Duty Investigation Initiation Checklist: Certain Fabricated Structural Steel from the People's Republic of China (China CVD Initiation Checklist); and Countervailing Duty Investigation Initiation Checklist: Certain Fabricated Structural Steel from Mexico (Mexico CVD Initiation Checklist). These checklists are dated concurrently with, and hereby adopted by, this notice and on file electronically via ACCESS. Access to documents filed via ACCESS is also available in the Central Records Unit, Room B8024 of the main Department of Commerce building.

[7] *See* Memorandum, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Imports of Certain Fabricated Structural Steel from Canada, the People's Republic of China, and Mexico: Phone Call with Counsel to the Petitioner,'' dated February 21, 2019; *see also* the petitioner's Letter, ''Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China: Revision to Scope,'' dated February 22, 2019.

[8] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[9] *See* 19 CFR 351.102(b)(21) (defining ''factual information'').

[10] *See* 19 CFR 351.303(b).

[11] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011); *see also Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

[12] *See* Commerce Letters, ''Certain Fabricated Structural Steel from Canada, Invitation for Consultations to Discuss the Countervailing Duty Petition'' dated February 5, 2019, ''Countervailing Duty Petition on Certain Fabricated Structural Steel from Mexico,'' dated February 6, 2019, and ''Countervailing Duty Petition on Certain Fabricated Structural Steel from the People's Republic of China,'' dated February 5, 2019.

[13] *See* Memorandum, ''Consultations with Officials from the Government of Canada Regarding the Countervailing Duty Petition Concerning Fabricated Structural Steel from Canada,'' and ''Ex-Parte Meeting with Officials from the Government of Mexico on the Countervailing Duty Petition on Certain Fabricated Structural Steel from Mexico,'' both dated February 19, 2019.

petition. Moreover, section 702(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, Commerce shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the ''industry.''

Section 771(4)(A) of the Act defines the ''industry'' as the producers, as a whole, of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs Commerce to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both Commerce and the ITC must apply the same statutory definition regarding the domestic like product,[14] they do so for different purposes and pursuant to a separate and distinct authority. In addition, Commerce's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[15]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, the petitioner does not offer a definition of the domestic like product distinct from the scope of the Petitions.[16] Based on our analysis of the information submitted on the record, we have determined that fabricated structural steel, as defined in the scope, constitutes a single domestic like product, and we have analyzed industry support in terms of that domestic like product.[17]

In determining whether the petitioner has standing under section 702(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of the Investigations,'' in the Appendix to this notice. To establish industry support, the petitioner provided its own production of the domestic like product in 2017.[18] The petitioner estimated the production of the domestic like product for the entire domestic industry based on shipment data, because production data for the entire domestic industry are not available, and shipments are a close approximation of production in the fabricated structural steel industry.[19] The petitioner compared its production to the estimated total production of the domestic like product for the entire domestic industry.[20] We relied on data provided by the petitioner for purposes of measuring industry support.[21]

From February 12 through February 13, 2019, we received comments on industry support from Canada, Quebec, and Mexico, respectively.[22] The petitioner responded to Canada's and Mexico's comments on February 19, 2019.[23]

On February 19, 2019, we received comments on industry support from Corey, S.A. de C.V. (Corey), a Mexican producer and exporter of fabricated structural steel.[24]

The petitioner responded to the comments from Corey on February 21, 2019.[25] In addition, the petitioner subsequently clarified and amended the Petitions on February 21, 2019 in response to comments from Canada, Mexico, and Corey.[26] During consultations held with respect to the Canada and Mexico CVD petitions, the both Canada and Mexico discussed industry support comments and provided additional comments in the respective CVD consultation papers.[27] On February 22, 2019, we received additional comments on industry support from Canada, Quebec and Mexico.[28] The petitioner responded to those comments on February 25, 2019.[29] For further discussion of these comments, *see* the country-specific CVD initiation checklists, at Attachment II.

Our review of the data provided in the Petitions, the General Issues Supplement, and other information readily available to Commerce indicates that the petitioner has established industry support for the Petitions.[30] First, the Petitions established support from domestic producers (or workers) accounting for more than 50 percent of

[14] *See* section 771(10) of the Act.

[15] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd.* v. *United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[16] *See* Volume I of the Petitions, at 14–16 and Exhibit I–5; *see also* General Issues Supplement, at 1–3.

[17] For a discussion of the domestic like product analysis as applied to these cases and information regarding industry support, *see* Canada CVD Initiation Checklist, at Attachment II, Analysis of Industry Support for the Antidumping and Countervailing Duty Petitions Covering Certain Fabricated Structural Steel from Canada, the People's Republic of China, and Mexico (Attachment II); *see also* China CVD Initiation Checklist, at Attachment II; Mexico CVD Initiation Checklist, at Attachment II.

[18] *See* Volume I of the Petitions, at 2–3 and Exhibit I–4.

[19] *Id.* at 2–3 and Exhibits I–3 and I–4; *see also* General Issues Supplement, at 3–6.

[20] *See* Volume I of the Petitions, at 2–3.

[21] *Id.* at 2–3 and Exhibit I–3 and I–4; *see also* General Issues Supplement, at 3–6. For further discussion, *see* Canada CVD Initiation Checklist, at Attachment II; China CVD Initiation Checklist, at Attachment II; and Mexico CVD Initiation Checklist, at Attachment II.

[22] *See* Mexico Letter, ''Fabricated Structural Steel from Mexico (A–201–850 and C–201–851)—Request to Dismiss Petitions or Otherwise Postpone Initiation,'' dated February 13, 2019; *see also* Canada Letter, ''Fabricated Structural Steel from Canada (A–122–864 and C–122–865)—Request for Postponement of Initiation and Disclosure of Members of Petitioner American Institute of Steel Construction and Identities of Known Domestic Producers,'' dated February 12, 2019; *see also* Mexico Letter, ''Fabricated Structural Steel from Mexico (C–201–851)—Submission of Consultations Paper,'' dated February 20, 2019.

[23] *See* the petitioner's Letter, ''Certain Fabricated Structural Steel from Canada and Mexico: Response to Respondents' Request to Reject Petitions or Postpone Initiation,'' dated February 19, 2019 (the petitioner's Response).

[24] *See* Letter from Corey, ''Fabricated Structural Steel from Mexico: Standing Challenge—Request to Decline Initiation of Antidumping and Countervailing Duty Investigations,'' dated February 19, 2019.

[25] *See* the petitioner's Letter, ''Certain Fabricated Structural Steel from Canada and Mexico: Response to Respondents' Standing Challenge and Request to Decline Initiation,'' dated February 21, 2019.

[26] *See* Amendment to the Petitions.

[27] *See* Ex-Parte Memorandum, ''Meeting with Officials from the Government of Mexico on the Countervailing Duty Petition on Certain Fabricated Structural Steel from Mexico'' dated February 19, 2019; *see also* Memorandum, ''Countervailing Duty Petition on Certain Fabricated Structural Steel from Canada: GOC Consultations,'' dated February 21, 2019; *see also* Letter from Mexico, ''Fabricated Structural Steel from Mexico (C–201–851)—Submission of Consultations Paper,'' dated February 20, 2019; *see also* Letter from Canada, ''Fabricated Structural Steel from Canada (A–122–864 and C–122–865)—Consultations Paper.

[28] *See* Letter from the GOQ, ''Fabricated Structural Steel from Canada, (A–122–864 and C–122–865): Response to AISC Amendment to Petition,'' dated February 22, 2019; *see also* Letter from Canada, ''Fabricated Structural Steel from Canada (A–122–864 and C–122–865)—Response to AISC Amendment to Petition,'' dated February 22, 2019; *see also* Letter from Mexico, ''Fabricated Structural Steel from Mexico (C–201–851, A–201–850)—Comments on Change of Petitioner,'' dated February 22, 2019.

[29] *See* Letter from the petitioner, ''Certain Fabricated Structural Steel from Canada, Mexico, and the People's Republic of China,'' dated February 25, 2019.

[30] *See* Canada CVD Initiation Checklist, at Attachment II; China CVD Initiation Checklist, at Attachment II; and Mexico CVD Initiation Checklist, at Attachment II.

the total production of the domestic like product and, as such, Commerce is not required to take further action in order to evaluate industry support (*e.g.,* polling).[31] Second, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(i) of the Act because the domestic producers (or workers) who support the Petitions account for at least 25 percent of the total production of the domestic like product.[32] Finally, the domestic producers (or workers) have met the statutory criteria for industry support under section 702(c)(4)(A)(ii) of the Act because the domestic producers (or workers) who support the Petitions account for more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions.[33] Accordingly, Commerce determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 702(b)(1) of the Act.

Commerce finds that the petitioner filed the Petitions on behalf of the domestic industry because it is an interested party as defined in section 771(9)(E) of the Act, and it has demonstrated sufficient industry support with respect to the CVD investigations that it is requesting that Commerce initiate.[34]

Injury Test

Because Canada, China, and Mexico are ''Subsidies Agreement Countries'' within the meaning of section 701(b) of the Act, section 701(a)(2) of the Act applies to these investigations. Accordingly, the ITC must determine whether imports of the subject merchandise from Canada, China, and/or Mexico materially injure, or threaten material injury to, a U.S. industry.

Allegations and Evidence of Material Injury and Causation

The petitioners allege that imports of the subject merchandise are benefitting from countervailable subsidies and that such imports are causing, or threaten to cause, material injury to the U.S. industry producing the domestic like product. In addition, the petitioner alleges that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[35]

The petitioner contends that the industry's injured condition is illustrated by the significant volume and increasing market share of subject imports; reduced market share of the U.S. industry; underselling and price depression or suppression; declines in production, shipments, and capacity utilization; negative impact on employment variables; decline in the domestic industry's financial performance; and lost sales and revenues.[36] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, causation, negligibility, as well as cumulation, and we have determined that these allegations are properly supported by adequate evidence, and meet the statutory requirements for initiation.[37]

Initiation of CVD Investigations

Based on the examination of the Petitions, we find that the Petitions meet the requirements of section 702 of the Act. Therefore, we are initiating CVD investigations to determine whether imports of fabricated structural steel from Canada, Mexico, and China benefit from countervailable subsidies conferred by the governments of these countries. In accordance with section 703(b)(1) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determination no later than 65 days after the date of this initiation.

Canada

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation on 43 of the 44 alleged programs. For a full discussion of the basis for our decision to initiate on each program, *see* Canada CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

Mexico

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation on 17 of the 19 alleged programs. For a full discussion of the basis for our decision to initiate on each program, *see* Mexico CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

China

Based on our review of the Petition, we find that there is sufficient information to initiate a CVD investigation, in whole or part, on 25 of the 26 alleged programs. For a full discussion of the basis for our decision to initiate on each program, *see* China CVD Initiation Checklist. A public version of the initiation checklist for this investigation is available on ACCESS.

Respondent Selection

In the Petitions, the petitioner named 50 companies in Canada,[38] 18 companies in Mexico,[39] and 220 companies in China,[40] as producers/exporters of fabricated structural steel. Commerce intends to follow its standard practice in CVD investigations and calculate company-specific subsidy rates in these investigations. In the event Commerce determines that the number of companies is large and it cannot individually examine each company based upon Commerce's resources, where appropriate, Commerce intends to select mandatory respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports of fabricated structural steel from Canada, Mexico, and China during the POI under the appropriate Harmonized Tariff Schedule of the United States numbers listed in the ''Scope of the Investigations,'' in the Appendix.

On February 20, 2019, Commerce released CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO and indicated that interested parties wishing to comment regarding the CBP data and respondent selection must do so within three business days of the publication date of the notice of initiation of these CVD investigations.[41]

[31] *Id.; see also* section 702(c)(4)(D) of the Act.

[32] *See* Canada CVD Initiation Checklist, at Attachment II; China CVD Initiation Checklist, at Attachment II; and Mexico CVD Initiation Checklist, at Attachment II.

[33] *Id.*

[34] *Id.*

[35] *See* Volume I of the Petitions, at 22 and Exhibit I–8.

[36] *Id.* at 11–35 and Exhibits I–3, I–5, I–8, I–10 through I–22.

[37] *See* Canada CVD Initiation Checklist, at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Antidumping and Countervailing Duty Petitions Covering Certain Fabricated Structural Steel from Canada, the People's Republic of China, and Mexico (Attachment III); *see also* China CVD Initiation Checklist, at Attachment III; *see also* Mexico CVD Initiation Checklist, at Attachment III.

[38] *See* Volume I of the Petition at Exhibit I–7.

[39] *Id.*

[40] *Id.*

[41] *See* Memorandum, ''Countervailing Duty Investigation of Certain Fabricated Structural Steel from Canada: Releasing U.S. Customs and Border Protection Data,'' Memorandum, ''Countervailing Duty Petition on Certain Fabricated Structural Steel from Mexico: Release of Customs Data from U.S. Customs and Border Protection,'' and Memorandum, ''Countervailing Duty Petition on Certain Fabricated Structural Steel from the People's Republic of China: Release of Customs Data from U.S. Customs and Border Protection,'' each dated February 20, 2019.

Commerce will not accept rebuttal comments regarding the CBP data or respondent selection.

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305(b). Instructions for filing such applications may be found on the Commerce's website at *http://enforcement.trade.gov/apo.*

Comments must be filed electronically using ACCESS. An electronically filed document must be received successfully, in its entirety, by ACCESS no later than 5:00 p.m. ET on the date noted above. We intend to finalize our decisions regarding respondent selection within 20 days of publication of this notice.

Distribution of Copies of the Petitions

In accordance with section 702(b)(4)(A)(i) of the Act and 19 CFR 351.202(f), copies of the public versions of the Petitions have been provided to Canada, China, and Mexico *via* ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petitions to each exporter named in the Petitions, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We will notify the ITC of our initiation, as required by section 702(d) of the Act.

Preliminary Determination by the ITC

The ITC will preliminarily determine, within 45 days after the date on which the Petitions were filed, whether there is a reasonable indication that imports of fabricated structural steel from Canada, China, and/or Mexico are materially injuring, or threatening material injury to, a U.S. industry.[42] A negative ITC determination in any country will result in the investigation being terminated with respect to that country.[43] Otherwise, these investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

Factual information is defined in 19 CFR 351.102(b)(21) as: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). Section 351.301(b) of Commerce's regulations requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted[44] and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct.[45] Time limits for the submission of factual information are addressed in 19 CFR 351.301, which provides specific time limits based on the type of factual information being submitted. Interested parties should review the regulations prior to submitting factual information in these investigations.

Extensions of Time Limits

Parties may request an extension of time limits before the expiration of a time limit established under 19 CFR 351.301, or as otherwise specified by the Secretary. In general, an extension request will be considered untimely if it is filed after the expiration of the time limit established under 19 CFR 351.301. For submissions that are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. ET on the due date. Under certain circumstances, we may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, we will inform parties in the letter or memorandum of the deadline (including a specified time) by which extension requests must be filed to be considered timely. An extension request must be made in a separate, stand-alone submission; under limited circumstances we will grant untimely-filed requests for the extension of time limits. Parties should review *Extension of Time Limits; Final Rule,* 78 FR 57790 (September 20, 2013), available at *http://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm,* prior to submitting factual information in these investigations.

Certification Requirements

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information.[46] Parties must use the certification formats provided in 19 CFR 351.303(g).[47] Commerce intends to reject factual submissions if the submitting party does not comply with the applicable certification requirements.

Notification to Interested Parties

Interested parties must submit applications for disclosure under APO in accordance with 19 CFR 351.305. On January 22, 2008, Commerce published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (January 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

This notice is issued and published pursuant to sections 702 and 777(i) of the Act and 19 CFR 351.203(c).

Dated: February 25, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—Scope of the Investigations

The merchandise covered by these investigations is carbon and alloy fabricated structural steel. Fabricated structural steel is made from steel in which: (1) Iron predominates, by weight, over each of the other contained elements; and (2) the carbon content is two percent or less by weight. Fabricated structural steel products are steel products that have been fabricated for erection or assembly into structures, including, but not limited to, buildings (commercial, office, institutional, and multi-family residential); industrial and utility projects; parking decks; arenas and convention centers; medical facilities; and ports, transportation and infrastructure facilities. Fabricated structural steel is manufactured from carbon and alloy (including stainless) steel products such as angles, columns, beams, girders, plates, flange shapes (including manufactured structural shapes utilizing welded plates as a substitute for rolled wide flange sections), channels, hollow structural section (HSS) shapes, base plates, and plate-work components. Fabrication includes, but is not limited to cutting, drilling, welding, joining, bolting, bending, punching, pressure fitting, molding, grooving, adhesion, beveling, and riveting and may include items such as fasteners, nuts, bolts, rivets, screws, hinges, or joints.

The inclusion, attachment, joining, or assembly of non-steel components with

[42] *See* section 703(a)(2) of the Act.

[43] *See* section 703(a)(1) of the Act.

[44] *See* 19 CFR 351.301(b).

[45] *See* 19 CFR 351.301(b)(2).

[46] *See* section 782(b) of the Act.

[47] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings,* 78 FR 42678 (July 17, 2013) (*Final Rule*); *see also* frequently asked questions regarding the *Final Rule,* available at *http://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.*

fabricated structural steel does not remove the fabricated structural steel from the scope.

Fabricated structural steel is covered by the scope of the investigations regardless of whether it is painted, varnished, or coated with plastics or other metallic or non-metallic substances and regardless of whether it is assembled or partially assembled, such as into modules, modularized construction units, or sub-assemblies of fabricated structural steel.

Subject merchandise includes fabricated structural steel that has been assembled or further processed in the subject country or a third country, including but not limited to painting, varnishing, trimming, cutting, drilling, welding, joining, bolting, punching, bending, beveling, riveting, galvanizing, coating, and/or slitting or any other processing that would not otherwise remove the merchandise from the scope of the investigations if performed in the country of manufacture of the fabricated structural steel.

Specifically excluded from the scope of these investigations are:

1. Fabricated steel concrete reinforcing bar (rebar) if: (i) It is a unitary piece of fabricated rebar, not joined, welded, or otherwise connected with any other steel product or part; or (ii) it is joined, welded, or otherwise connected only to other rebar.

2. Fabricated structural steel for bridges and bridge sections that meets American Association of State and Highway and Transportation Officials (AASHTO) bridge construction requirements or any state or local derivatives of the AASHTO bridge construction requirements.

3. Pre-engineered metal building systems, which are defined as complete metal buildings that integrate steel framing, roofing and walls to form one, pre-engineered building system, that meet Metal Building Manufacturers Association guide specifications. Pre-engineered metal building systems are typically limited in height to no more than 60 feet or two stories.

4. Steel roof and floor decking systems that meet Steel Deck Institute standards.

5. Open web steel bar joists and joist girders that meet Steel Joist Institute specifications.

The products subject to the investigations are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings: 7308.90.3000, 7308.90.6000, and 7308.90.9590.

The products subject to the investigations may also enter under the following HTSUS subheadings: 7216.91.0010, 7216.91.0090, 7216.99.0010, 7216.99.0090, 7222.40.6000, 7228.70.6000, 7301.10.0000, 7301.20.1000, 7301.20.5000, 7308.40.0000, 7308.90.9530, and 9406.90.0030.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of the investigations is dispositive.

[FR Doc. 2019–03819 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–433–812]

Certain Carbon and Alloy Steel Cut-to-Length Plate From Austria: Notice of Court Decision Not in Harmony With Final Determination in Less Than Fair Value Investigation and Notice of Amended Final Determination and Order Pursuant to Court Decision

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On February 12, 2019, the United States Court of International Trade (CIT or the Court) sustained the final results of redetermination pertaining to the less-than-fair-value (LTFV) investigation of certain carbon and alloy steel cut-to-length plate (CTL plate) from Austria for the period of investigation from April 1, 2015, through March 31, 2016. The Department of Commerce (Commerce) is notifying the public that the final judgment in this case is not in harmony with the *Final Determination* and *Order* of the investigation and that Commerce is amending the *Final Determination* and *Order* with respect to the cash deposit rate assigned to voestalpine Grobblech GmbH, voestalpine Steel Service Center GmbH, Bohler Edelstahl GmbH & Co KG, Bohler Bleche GmbH & Co KG, and Bohler International GmbH, (collectively, voestalpine) and the all-others rate.

DATES: Applicable February 22, 2019.

FOR FURTHER INFORMATION CONTACT: Madeline Heeren, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9179.

SUPPLEMENTARY INFORMATION:

Background

On April 4, 2017, Commerce published its affirmative *Final Determination* of sales at less than fair value, in which it determined a weighted-average dumping margin of 53.72 percent for voestalpine.[1] The antidumping duty order was published on May 25, 2017.[2] The *Final Determination* was appealed to the CIT by voestalpine, and on July 9, 2018, the CIT sustained, in part, and remanded, in part, Commerce's *Final Determination.*[3] Specifically, the Court remanded the *Final Determination* directing Commerce to design a model-match methodology that accounts for commercially significant physical differences among products due to alloy content and to recalculate dumping margins in accordance with the revised model-match methodology.[4] On October 9, 2018, Commerce issued its final results of redetermination pursuant to remand in accordance with the CIT's order.[5] On remand, Commerce, under respectful protest,[6] used the alternative model-match methodology voestalpine proposed during the investigation to account for all commercially significant physical differences, including alloy content, and recalculated voestalpine's weighted-average dumping margin and the all-others rate using the revised model-match methodology.[7] On February 12, 2019, the CIT sustained Commerce's *Remand Redetermination.*[8] Therefore, the effective date of this notice is February 22, 2019.

Timken Notice

In its decision in *Timken,*[9] as clarified by *Diamond Sawblades,*[10] the United States Court of Appeals for the Federal Circuit (CAFC) held that, pursuant to section 516A of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not ''in harmony'' with a Commerce

[1] In accordance with section 771(33)(F) of the Act, we determined that the following companies were affiliated and should be treated as a single entity for purposes of the investigation: voestalpine Grobblech, voestalpine Steel Service Center GmbH, Bohler Edelstahl GmbH & Co KG, Bohler Bleche GmbH & Co KG, and Bohler International GmbH. *See Certain Carbon and Alloy Steel Cut-To-Length Plate from Austria: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 82 FR 16366, 16367 (April 4, 2017) (*Final Determination*) and accompanying Issues and Decision Memorandum (IDM).

[2] *See Certain Carbon and Alloy Steel Cut-To-Length Plate from Austria, Belgium, France, the Federal Republic of Germany, Italy, Japan, the Republic of Korea, and Taiwan: Amended Final Affirmative Antidumping Determinations for France, the Federal Republic of Germany, the Republic of Korea and Taiwan, and Antidumping Duty Orders,* 82 FR 24096 (May 25, 2017) (*Order*).

[3] *See Bohler Bleche GmbH & Co. KG, et al.,* v. *United States,* 324 F. Supp. 3d 1344 (CIT July 9, 2018) (*Bohler*)

[4] *Id.* at 1354–1355.

[5] *See* Final Results of Redetermination Pursuant to Court Order *Bohler Bleche GmbH & Co. KG,* v. *United States,* Court No. 17–00163, Slip Op. 18–86 (CIT July 9, 2018), dated October 9, 2018 (*Remand Redetermination*), available at *http://enforcement.trade.gov/remands/index.html.*

[6] *See Viraj Grp., Ltd.* v. *United States,* 343 F.3d 1371, 1376 (Fed. Cir. 2003).

[7] *See Remand Redetermination.*

[8] *See Bohler Bleche GmbH & Co. KG, et al.,* v. *United States,* Court No. 17–00163, Slip Op. 19–19 (CIT February 12, 2019).

[9] *See Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

[10] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

determination and must suspend liquidation of entries pending a ''conclusive'' court decision.[11] The CIT's February 12, 2019 judgment sustaining Commerce's *Remand Redetermination* constitutes a final decision of the Court that is not in harmony with Commerce's *Final Determination* and *Order.* This notice is published in fulfillment of the publication requirements of *Timken* and section 516A of the Act.

Amended Final Determination and Amended Order

Because there is now a final court decision, Commerce is amending the *Final Determination* and *Order* with respect to the margin assigned to voestalpine and all other producers and exporters. The revised weight-averaged dumping margin for voestalpine and the all-others rate for the period April 1, 2015, through March 31, 2016, are as follows:

Producer/exporter	Weighted-average dumping margin (percent)
Bohler Bleche GmbH & Co KG	28.57
Bohler Edelstahl GmbH & Co KG	
Bohler International GmbH	
voestalpine Grobblech GmbH	
voestalpine Steel Service Center GmbH	
All-Others	28.57

Cash Deposit Requirements

Because voestalpine does not have a superseding cash deposit rate, *i.e.,* there have been no final results published in subsequent administrative reviews for voestalpine, Commerce will instruct U.S. Customs and Border Protection (CBP) to collect the revised cash deposit rates listed above for voestalpine and companies covered by the all-others rate, effective February 22, 2019.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c)(1) and (e), 735(c)(1)(B), and 777(i)(1) of the Act.

Dated: February 26, 2019.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2019–03822 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–DS–P

[11] *See* Sections 516A(c) and (e) of the Act.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–485–805]

Carbon and Alloy Seamless Standard, Line and Pressure Pipe (Under 4.5 Inches) From Romania: Partial Rescission of Antidumping Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review, in part, of the antidumping duty order on carbon and alloy seamless standard, line and pressure pipe (under 4.5 inches) (small diameter seamless pipe) from Romania for the period August 1, 2017 through July 31, 2018.

DATES: Applicable March 4, 2019.

FOR FURTHER INFORMATION CONTACT: Katherine Johnson or Samantha Kinney, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4929 or 202–482–2285 respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 4, 2018, based on a timely request for review of four companies by United States Steel Corporation (the petitioner),[1] Commerce published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on small diameter seamless pipe from Romania covering the period August 1, 2017, through July 31, 2018.[2]

On February 13, 2019, the petitioner withdrew its request for administrative review of SC TMK-Artrom S.A. (TMK-Artrom).[3] No other interested parties requested an administrative review of this company.

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the publication of the notice of initiation of the requested review. Commerce exercised its discretion to toll all deadlines affected by the partial Federal Government closure from December 22, 2018, through the resumption of operations on January 29, 2019.[4] If the new deadline falls on a non-business day, in accordance with Commerce's practice, the deadline will become the next business day. In this case, the original deadline for parties to withdraw requests for administrative review of January 2, 2019, was extended prior to the partial Federal Government closure to January 9, 2019.[5] Therefore, the revised deadline to withdraw a review request was February 19, 2019.

Because the petitioner's request for administrative review of TMK-Artrom was withdrawn within 90 days of the date of publication of the *Initiation Notice* (as extended and tolled, per the discussion above), and no other interested party requested a review of this company, Commerce is rescinding this review with respect to TMK-Artrom, in accordance with 19 CFR 351.213(d)(1). The administrative review remains active with respect to all other companies initiated for review, *i.e.,* ArcelorMittal Tubular Products Roman S.A.; SC Tubinox S.A.; and Silcotub S.A.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries at a rate equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period August 1, 2017, through July 31, 2018, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice in the **Federal Register**, if appropriate.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries

[1] *See* Petitioner's Letter, ''Carbon and Alloy Seamless Standard Line, and Pressure Pipe (Under 4.5 Inches) from Romania: Request for Administrative Review of Antidumping Duty Order,'' dated August 30, 2018.

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 50077 (October 4, 2018) (*Initiation Notice*).

[3] *See* Petitioner's Letter, ''Carbon and Alloy Seamless Standard Line, and Pressure Pipe (Under 4.5 Inches) from Romania: Partial Withdrawal of Request for Administrative Review of Antidumping Duty Order,'' dated February 13, 2019.

[4] *See* Memorandum, ''Deadlines Affected by the Partial Shutdown of the Federal Government,'' dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

[5] *See* Commerce Letter re: Request for Extension, dated December 21, 2018.

during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: February 26, 2019.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–03817 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Manufacturing Extension Partnership Advisory Board

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) announces that the Manufacturing Extension Partnership (MEP) Advisory Board will hold an open meeting on March 29, 2019.

DATES: The meeting will be held Friday, March 29, 2019, from 8:00 a.m. to 4:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held at the Reagan Building at 1300 Pennsylvania Ave. NW, Washington, DC 20004. Please note admittance instructions in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: Cheryl L. Gendron, Manufacturing Extension Partnership, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, Maryland 20899–4800, telephone number (301) 975–2785, email: *cheryl.gendron@nist.gov*.

SUPPLEMENTARY INFORMATION: The MEP Advisory Board is authorized under Section 3003(d) of the America COMPETES Act (Pub. L. 110–69), as amended by the American Innovation and Competitiveness Act, Public Law 114–329 sec. 501 (2017), and codified at 15 U.S.C. 278k(m), in accordance with the provisions of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. The Hollings MEP Program (Program) is a unique program, consisting of centers in all 50 states and Puerto Rico with partnerships at the state, federal, and local levels. By statute, the MEP Advisory Board provides the NIST Director with: (1) Advice on the activities, plans, and policies of the Program; (2) assessments of the soundness of the plans and strategies of the Program; and (3) assessments of current performance against the plans of the Program.

Background information on the MEP Advisory Board is available at *http://www.nist.gov/mep/about/advisory-board.cfm*.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the MEP Advisory Board will hold an open meeting on Friday, March 29, 2019, from 8:00 a.m. to 4:00 p.m. Eastern Time. The meeting agenda will include an update on Hollings MEP programmatic operations, as well as provide guidance and advice on current activities related to the 2017–2022 MEP National Network Strategic Plan. The MEP Advisory Board will provide input to NIST on supply chain development with an emphasis on defense suppliers, in order to strengthen the defense industrial base; make recommendations on the development of research and performance metrics to support and enrich MEP Center evaluation; and receive updates from external organizations that work closely with the Program regarding national and state economic challenges, opportunities, and data trends. The final agenda will be posted on the MEP Advisory Board website at *http://www.nist.gov/mep/about/advisory-board.cfm*.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the MEP Advisory Board's business are invited to request a place on the agenda. Approximately 15 minutes will be reserved for public comments at the end of the meeting. Speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received but is likely to be no more than three to five minutes each. Requests must be received in writing by March 22, 2019 to be considered. The exact time for public comments will be included in the final agenda that will be posted on the MEP Advisory Board website at *http://www.nist.gov/mep/about/advisory-board.cfm*. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who wished to speak but could not be accommodated on the agenda, or those who are/were unable to attend in person are invited to submit written statements to the MEP Advisory Board, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 4800, Gaithersburg, Maryland 20899–4800, via fax at (301) 963–6556, or electronically by email to *cheryl.gendron@nist.gov*.

Admittance Instructions: Anyone wishing to attend the MEP Advisory Board meeting must submit their name, email address and phone number to Cheryl Gendron (*Cheryl.Gendron@nist.gov* or 301–975–2785) no later than Wednesday, March 27, 2019, 5:00 p.m. Eastern Time.

Kevin A. Kimball,

Chief of Staff.

[FR Doc. 2019–03753 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

NIST Smart Grid Advisory Committee Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Institute of Standards and Technology (NIST) Smart Grid Advisory Committee (SGAC or Committee) will hold an open meeting on Tuesday, April 2, 2019 from 11:00 a.m. to 1:00 p.m. Eastern Time via teleconference and/or webinar.

DATES: The SGAC will meet on Tuesday, April 2, 2019 from 11:00 a.m. to 1:00 p.m. Eastern Time via teleconference and/or webinar.

ADDRESSES: The meeting will be held via teleconference and/or webinar. For

instructions on how to participate in the meeting via teleconference and/or webinar, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Cuong Nguyen, Smart Grid and Cyber-Physical Systems Program Office, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8200, Gaithersburg, MD 20899–8200; telephone 301–975–2254, fax 301–948–5668. Mr. Nguyen's email address is *cuong.nguyen@nist.gov.*

SUPPLEMENTARY INFORMATION: The Committee was established in accordance with the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that that SGAC will meet via teleconference and/or webinar on Tuesday, April 2, 2019 from 11:00 a.m. to 1:00 p.m. Eastern Time. There will be no central meeting location. The meeting will be open to the public. The public is invited to participate in the meeting by calling in from remote locations. The Committee is composed of nine to fifteen members, appointed by the Director of NIST, who were selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting Smart Grid deployment and operations. The Committee advises the Director of NIST in carrying out duties authorized by section 1305 of the Energy Independence and Security Act of 2007 (Pub. L. 110–140). The Committee provides input to NIST on Smart Grid standards, priorities, and gaps, on the overall direction, status, and health of the Smart Grid implementation by the Smart Grid industry, and on the direction of Smart Grid research and standards activities. Background information on the Committee is available at *http://www.nist.gov/smartgrid/.*

The primary purposes of this meeting are to provide updates on the subcommittees' activities and stakeholder engagement for the NIST Framework and Roadmap for Smart Grid Interoperability Standards, Release 4.0. The agenda may change to accommodate Committee business. The final agenda will be posted on the Smart Grid website at *http://www.nist.gov/smartgrid.*

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's affairs are invited to request a place on the agenda by submitting their request to Cuong Nguyen at *cuong.nguyen@nist.gov* or (301) 975–2254 no later than 5:00 p.m. Eastern Time, Tuesday, March 19, 2019. On Tuesday, April 2, 2019, approximately fifteen minutes will be reserved at the end of the meeting for public comments, and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received but is likely to be about three minutes each. Questions from the public will not be considered during this period. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to Mr. Cuong Nguyen, Smart Grid and Cyber-Physical Systems Program Office, National Institute of Standards and Technology, 100 Bureau Drive, Mail Stop 8200, Gaithersburg, MD 20899–8200; telephone 301–975–2254, fax 301–948–5668; or via email at *cuong.nguyen@nist.gov,* by 5:00 p.m. Eastern Time, Tuesday, March 19, 2019.

All meeting participants are required to pre-register. Anyone wishing to participate must register by 5:00 p.m. ET on Tuesday, March 19, 2019, in order to be included. Please submit your name, email address, and phone number to Cuong Nguyen at *cuong.nguyen@nist.gov* or (301) 975–2254. After pre-registering, participants will be provided with detailed instructions on how to join the teleconference/webinar from a remote location in order to participate.

Kevin Kimball,

NIST Chief of Staff.

[FR Doc. 2019–03754 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Open Meeting of the Information Security and Privacy Advisory Board

AGENCY: National Institute of Standards and Technology.

ACTION: Notice.

SUMMARY: The Information Security and Privacy Advisory Board (ISPAB) will meet Wednesday, March 20, 2019 from 9:00 a.m. until 5:00 p.m., Eastern Time, and Thursday, March 21, 2019 from 9:00 a.m. until 4:30 p.m. Eastern Time. All sessions will be open to the public.

DATES: The meeting will be held on Wednesday, March 20, 2019, from 9:00 a.m. until 5:00 p.m., Eastern Time, and Thursday, March 21, 2019, from 9:00 a.m. until 4:30 p.m. Eastern Time.

ADDRESSES: The meeting will be held at Symantec, 700 13th St. NW, Washington, DC 20005. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Jeff Brewer, Information Technology Laboratory, NIST, 100 Bureau Drive, Stop 8930, Gaithersburg, MD 20899–8930, Telephone: (301) 975–2489, Email address: *jeffrey.brewer@nist.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the ISPAB will meet Wednesday, March 20, 2019, from 9:00 a.m. until 5:00 p.m., Eastern Time, and Thursday, March 21, 2019 from 9:00 a.m. until 4:30 p.m. Eastern Time. All sessions will be open to the public. The ISPAB is authorized by 15 U.S.C. 278g–4, as amended, and advises the National Institute of Standards and Technology (NIST), the Secretary of Homeland Security, and the Director of the Office of Management and Budget (OMB) on information security and privacy issues pertaining to Federal government information systems, including thorough review of proposed standards and guidelines developed by NIST. Details regarding the ISPAB's activities are available at *http://csrc.nist.gov/groups/SMA/ispab/index.html.*

The agenda is expected to include the following items:

—Briefing on the U.S. Government Supply Chain Risk Management Council,
—Briefing from Health and Human Services on their Healthcare Cybersecurity Program,
—Briefing on AI and cybersecurity,
—Briefing on Global Positioning System cybersecurity,
—Briefing on the Department of Homeland Security Emergency Directive,
—Briefing on transitions from internet Protocols Version (IPV) 4 to IPV 6.

Note that agenda items may change without notice. The final agenda will be posted on the website indicated above. Seating will be available for the public and media. Pre-registration is not required to attend this meeting.

Public Participation: The ISPAB agenda will include a period, not to exceed thirty minutes, for oral comments from the public (Wednesday, March 20, 2019, between 4:30 p.m. and 5:00 p.m.). Speakers will be selected on a first-come, first-served basis. Each speaker will be limited to five minutes.

Questions from the public will not be considered during this period. Members of the public who are interested in speaking are requested to contact Jeff Brewer at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements. In addition, written statements are invited and may be submitted to the ISPAB at any time. All written statements should be directed to the ISPAB Secretariat, Information Technology Laboratory, 100 Bureau Drive, Stop 8930, National Institute of Standards and Technology, Gaithersburg, MD 20899–8930.

Pre-registration, which is not required, may expedite the entrance process. Please email Jeff Brewer at *Jeffrey.Brewer@nist.gov* by March 19, 2019 to pre-register.

Kevin A. Kimball,

Chief of Staff.

[FR Doc. 2019–03755 Filed 3–1–19; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF DEFENSE

Department of the Navy

Meeting of the Board of Advisors (BOA) to the President of the Naval Postgraduate School (NPS) Subcommittee

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the following Federal Advisory Committee meeting of the President of the Naval Postgraduate School Subcommittee Board of Advisors will be held. This meeting will be open to the public.

DATES: The meeting will be held on Wednesday, April 24, 2019 from 8:00 a.m. to 4:30 p.m. and on Thursday, April 25, 2019 from 7:30 a.m. to 11:30 a.m. Pacific Time Zone.

ADDRESSES: The meeting will be held at the Naval Postgraduate School, Executive Briefing Center, Herrmann Hall, 1 University Circle, Monterey, CA.

FOR FURTHER INFORMATION CONTACT: Ms. Jaye Panza, Designated Federal Official, 1 University Circle, Code 00H, Monterey, CA 93943–5001, telephone number 831–656–2514.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150. The purpose of the Board is to advise and assist the President, NPS, in educational and support areas, providing independent advice and recommendations on items such as, but not limited to, organizational management, curricula, methods of instruction, facilities, and other matters of interest.

The agenda for Wednesday is as follows:

8:00 a.m.–8:15 a.m.: Call to Order, Chairman Instructions

8:15 a.m.–8:45 a.m.: Annual Ethics Brief

8:45 a.m.–9:45 a.m.: NPS President's Update

9:45 a.m.–10:00 a.m.: Break

10:00 a.m.–10:45 a.m.: NPS Provost's Update

10:45 a.m.–11:45 a.m.: Roundtable Discussion

11:45 a.m.–1:15 p.m.: Meet with NPS Students

1:15 p.m.–1:30 p.m.: Break

1:30 p.m.–2:30 p.m.: NPS Foundation

2:30 p.m.–4:30 p.m.: Board Discussion

The agenda for Thursday is as follows:

7:30 a.m.–8:30 a.m.: Meet with NPS Faculty

8:30 a.m.–11:30 a.m.: Board Discussion

11:30 a.m.: Meeting Adjourned

Individuals without a DoD Government Common Access Card require an escort at the meeting location. The meeting is accessible to persons with disabilities. For access, information, reasonable accommodation requests, or to send written statements for consideration at the committee meeting contact Ms. Jaye Panza, Designated Federal Officer, Naval Postgraduate School, 1 University Circle, Monterey, CA 93943–5001 or by fax (831) 656–2337 by April 15, 2019.

(Authority: 5 U.S.C. 552b)

Dated: February 27, 2019.

M.S. Werner,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2019–03787 Filed 3–1–19; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2018–ICCD–0128]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Federal Student Aid (FSA) Feedback System

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before April 3, 2019.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2018–ICCD–0128. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the

Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Student Aid (FSA) Feedback System.

OMB Control Number: 1845–0141.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 43,200.

Total Estimated Number of Annual Burden Hours: 7,344.

Abstract: This is a request for extension of the current information collection of the FSA Feedback System, OMB Control 1845–0141. On March 10, 2015, the White House issued a Student Aid Bill of Rights. Among the objectives identified was the creation of a centralized complaint system that is now resident and supported via the Federal Student Aid/Customer Engagement Management System. The purpose of the Customer Engagement Management System (CEMS) is to meet the objective: ''Create a Responsive Student Feedback System: The Secretary of Education will create a new website by July 1, 2016, to give students and borrowers a simple and straightforward way to file complaints and provide feedback about federal student loan lenders, servicers, collections agencies, and institutions of higher education. Students and borrowers will be able to ensure that their complaints will be directed to the right party for timely resolution, and the Department of Education will be able to more quickly respond to issues and strengthen its efforts to protect the integrity of the student financial aid programs.''

Dated: February 27, 2019.

Kate Mullan,

PRA Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019–03814 Filed 3–1–19; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Request for Comments: Performance of Accrediting Agencies

AGENCY: Accreditation Group, Office of Postsecondary Education, U.S. Department of Education.

ACTION: Call for written third-party comments.

SUMMARY: This notice provides information to members of the public on submitting written comments for accrediting agencies currently undergoing review for purposes of recognition by the U.S. Secretary of Education.

FOR FURTHER INFORMATION CONTACT: Herman Bounds, Director, Accreditation Group, Office of Postsecondary Education, U.S. Department of Education, 400 Maryland Avenue SW, Room 270–01, Washington, DC 20202, telephone: (202) 453–7615, or email: *herman.bounds@ed.gov.*

SUPPLEMENTARY INFORMATION: This solicitation of written third-party comments concerning the performance of accrediting agencies under review by the Secretary of Education is required by § 496(n)(1)(A) of the Higher Education Act (HEA) of 1965, as amended, and pertains to the Summer 2019 meeting of the National Advisory Committee on Institutional Quality and Integrity (NACIQI). The meeting date and location have not been determined, but will be announced in a later **Federal Register** notice. Also, a later **Federal Register** notice will describe how to register to provide oral comments at the meeting.

Agencies Under Review and Evaluation: The Department requests written comments from the public on the following accrediting agencies, which are currently undergoing review and evaluation by the Accreditation Group, and which will be reviewed at the Summer NACIQI meeting. The agencies are listed, with their current and requested scope of recognition, by the type of application each has submitted:

Applications for Renewal of Recognition

1. National Association of Schools of Dance, Commission on Accreditation. Scope of recognition: The accreditation throughout the United States of freestanding institutions that offer dance and dance-related programs (both degree and non-degree-granting), including those offered via distance education.

2. National Association of Schools of Music, Commission on Accreditation. Scope of recognition: The accreditation throughout the United States of freestanding institutions that offer music and music related programs (both degree and non-degree-granting), including those offered via distance education.

3. National Association of Schools of Theatre, Commission on Accreditation. Scope of recognition: The accreditation throughout the United States of freestanding institutions that offer theatre and theatre-related programs (both degree and non-degree-granting), including those offered via distance education.

Compliance Report

1. Southern Association of Colleges and Schools, Commission on Colleges. Compliance report includes the following: Finding identified in the September 20, 2017 letter from the senior Department official following the June 20, 2017 NACIQI meeting available at: *https://opeweb.ed.gov/aslweb/finalstaffreports.cfm,* with respect to recognition requirements found at 34 CFR § 602.15(a)(2). Scope of recognition: The accreditation and preaccreditation (''Candidate for Accreditation'') of degree-granting institutions of higher education in Alabama, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Texas, and Virginia, including the accreditation of programs offered via distance and correspondence education within these institutions. This recognition extends to the SACSCOC Board of Trustees and the Appeals Committee of the College Delegate Assembly on cases of initial candidacy or initial accreditation and for continued accreditation or candidacy.

2. Middle States Commission on Secondary Schools. Compliance report includes the following: Finding identified in the September 20, 2017 letter from the senior Department official following the June 20, 2017 NACIQI meeting available at: *https://opeweb.ed.gov/aslweb/finalstaffreports.cfm,* with respect to recognition requirements found at 34

CFR 602.15(a)(1) and 602.15(a)(2). Scope of recognition: The accreditation of institutions with postsecondary, non-degree granting career and technology programs in Delaware, Maryland, New Jersey, New York, Pennsylvania, the Commonwealth of Puerto Rico, the District of Columbia, and the U.S. Virgin Islands to include the accreditation of postsecondary, non-degree granting institutions that offer all or part of their educational programs via distance education modalities.

Application for an Expansion of Scope

1. Association for Clinical Pastoral Education, Inc. Scope of Recognition: The accreditation of both clinical pastoral education (CPE) centers and supervisory CPE programs located within the United States and territories

Requested Scope of Recognition: The provisional accreditation and accreditation of both clinical pastoral education (CPE) centers and certified educator CPE programs within the United States and territories, including those that offer those programs via distance education.

Application for Initial Recognition

1. National League for Nursing Commission for Nursing Education Accreditation. Requested Scope of Recognition: The pre-accreditation and accreditation of nursing education programs, in the United States and its territories, which offer a certificate, diploma or degree at the practical/vocational, diploma, associate, baccalaureate, masters, doctoral levels, including those offered via distance education.

Submission of Written Comments Regarding a Specific Accrediting Agency or State Approval Agency Under Review

Written comments about the recognition of one of the accrediting or State agencies listed above must be received by March 30, 2019, in the *ThirdPartyComments@ed.gov* mailbox and include the subject line ''Written Comments: (agency name).'' The email must include the name(s), title, organization/affiliation, mailing address, email address, and telephone number of the person(s) making the comment. Comments should be submitted as a Microsoft Word document or in a medium compatible with Microsoft Word (not a PDF file) that is attached to an electronic mail message (email) or provided in the body of an email message. Comments about an agency that has submitted a compliance report scheduled for review by the Department must relate to the criteria for recognition cited in the senior Department official's letter that requested the report, or in the Secretary's appeal decision, if any. Comments about an agency that has submitted a petition for initial recognition, renewal of recognition, or an expansion of scope must relate to the agency's compliance with the Criteria for the Recognition of Accrediting Agencies, which are available at *http://www.ed.gov/admins/finaid/accred/index.html.*

Only written material submitted by the deadline to the email address listed in this notice, and in accordance with these instructions, become part of the official record concerning agencies scheduled for review and are considered by the Department and NACIQI in their deliberations.

Note: In addition to the agencies listed above, the agenda for the Summer 2019 NACIQI meeting includes all accrediting agencies that were scheduled to appear at the Winter 2019 NACIQI meeting. The Winter 2019 NACIQI meeting was cancelled due to the lapse in appropriations. The solicitation of third-party comments for those accrediting agencies was announced in the **Federal Register** notice (83 FR 44869–44870), dated September 4, 2018. The written comment period for those accrediting agencies has closed. The final staff reports for those agencies have been released and are available at: *https://opeweb.ed.gov/aslweb/finalstaffreports.cfm.*

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: 20 U.S.C. 1011c.

Lynn B. Mahaffie,

Deputy Assistant Secretary for Planning, Policy, and Innovation.

[FR Doc. 2019–03733 Filed 3–1–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Methane Hydrate Advisory Committee

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Methane Hydrate Advisory Committee. The Federal Advisory Committee Act requires that notice of these meetings be announced in the **Federal Register**.

DATES:

Tuesday, April 23, 2019

8:30 a.m. to 9:00 p.m. (CST)—Registration
9:00 a.m. to 5:00 p.m. (CST)—Meeting

Wednesday, April 24, 2019

8:30 a.m. to 5:00 p.m. (CST)—Meeting

ADDRESSES: Hilton Americas-Houston, 1600 Lamar; Room 337, Houston, Texas 77010.

FOR FURTHER INFORMATION CONTACT: Gabby Intihar, U.S. Department of Energy, Office of Oil and Natural Gas, 1000 Independence Avenue SW, Washington, DC 20585. *Phone:* (202) 586–2092.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The purpose of the Methane Hydrate Advisory Committee is to provide advice on potential applications of methane hydrate to the Secretary of Energy, and assist in developing recommendations and priorities for the Department of Energy's Methane Hydrate Research and Development Program.

Tentative Agenda: The agenda will include: Welcome and Introduction by the Designated Federal Officer; Committee Business; Committee Chair Update to Secretary's November 12th Letter; Update on Methane Hydrate National Energy Technology Laboratory Research Innovation Center Activities; Overview of Major Projects Alaska North Slope and Gulf of Mexico; Advisory Committee Gas Hydrates Roadmap Development and Discussion; and Public Comments, if any.

Public Participation: The meeting is open to the public. The Designated Federal Officer and the Chair of the Committee will conduct the meeting to facilitate the orderly conduct of business. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Gabby Intihar at the phone number listed above and provide your name,

organization, citizenship, and contact information. Anyone attending the meeting will be required to present government-issued identification. Space is limited. You must make your request for an oral statement at least five business days prior to the meeting, and reasonable provisions will be made to include the presentation on the agenda. Public comment will follow the three-minute rule.

Minutes: The minutes of this meeting will be available for public review and copying within 60 days at the following website: *http://energy.gov/fe/services/advisory-committees/methane-hydrate-advisory-committee.*

Signed in Washington, DC, on February 22, 2019.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–03808 Filed 3–1–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board Chairs

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB) Chairs. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES:

Wednesday, May 8, 2019

8:00 a.m.–5:00 p.m.

Thursday, May 9, 2019

9:00 a.m.–12:00 p.m.

ADDRESSES: City of Aiken Municipal Building, Conference Center, 215 The Alley SW, Aiken, South Carolina 29801.

FOR FURTHER INFORMATION CONTACT: David Borak, EM SSAB Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585; Phone: (202) 586–9928.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda Topics

Wednesday, May 8, 2019

- EM Program Update
- EM SSAB Chairs' Round Robin
- Waste Disposition and Regulatory Affairs Update
- Budget and Planning Update
- Public Comment
- Board Business

Thursday, May 9, 2019

- DOE Headquarters News and Views
- Field Operations Update
- Public Comment
- Board Business

Public Participation: The meeting is open to the public. The EM SSAB Chairs welcome the attendance of the public at their advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact David Borak at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed either before or after the meeting with the Designated Federal Officer, David Borak, at the address or telephone listed above. Individuals who wish to make oral statements pertaining to agenda items should also contact David Borak. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling David Borak at the address or phone number listed above. Minutes will also be available at the following website: *https://energy.gov/em/listings/chairs-meetings.*

Signed in Washington, DC, on February 22, 2019.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–03811 Filed 3–1–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL19–49–000]

Notice of Filing; Cooperative Energy

Take notice that on February 25, 2019, Cooperative Energy filed a proposed revenue requirement filing for reactive supply service for its Batesville Combined Cycle and Grand Gulf Nuclear Generating Facilities, under Midcontinent Independent Transmission System Operator Inc. Tariff Schedule 2.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the eLibrary link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on March 18, 2019.

Dated: February 26, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03762 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–162–001.

Applicants: Mendota Hills, LLC.

Description: Notice of Non-Material Change in Facts of Mendota Hills, LLC.

Filed Date: 2/22/19.

Accession Number: 20190222–5098.
Comments Due: 5 p.m. ET 3/15/19.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG19–62–000.
Applicants: Brickyard Hills Project, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Brickyard Hills Project, LLC.
Filed Date: 2/21/19.
Accession Number: 20190221–5262.
Comments Due: 5 p.m. ET 3/14/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–632–008; ER14–2140 008; ER14–2141 008; ER14–2465 009; ER14–2466 009; ER14–2939 006; ER15–1952 006; ER15–2728 008; ER15–634 008.
Applicants: CID Solar, LLC, Cottonwood Solar, LLC, RE Camelot LLC, RE Columbia Two LLC, Pavant Solar LLC, Imperial Valley Solar Company (IVSC) 2, LLC, Maricopa West Solar PV, LLC, Mulberry Farm, LLC, Selmer Farm, LLC.
Description: Notice of Non-material Change in Status of the Dominion Companies.
Filed Date: 2/21/19.
Accession Number: 20190221–5307.
Comments Due: 5 p.m. ET 3/14/19.

Docket Numbers: ER19–709–001.
Applicants: Entergy Louisiana, LLC.
Description: Tariff Amendment: Entergy OpCos Reactive Power Update to be effective 1/1/2019.
Filed Date: 2/22/19.
Accession Number: 20190222–5087.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–714–001.
Applicants: Tucson Electric Power Company.
Description: Tariff Amendment: Request for Deferral of Commission Action to be effective 12/31/9998.
Filed Date: 2/22/19.
Accession Number: 20190222–5038.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1097–000.
Applicants: Northern States Power Company, a Minnesota corporation.
Description: Notice of cancellation of Connection Agreement of Northern States Power Company, a Minnesota corporation.
Filed Date: 2/21/19.
Accession Number: 20190221–5291.
Comments Due: 5 p.m. ET 3/14/19.

Docket Numbers: ER19–1098–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–02–22_SA 3252 MRES-Deuel Harvest Wind Energy FCA (J526) to be effective 2/12/2019.
Filed Date: 2/22/19.
Accession Number: 20190222–5012.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1099–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: First Revised ISA, SA 3610; Queue No. AD1–114 to be effective 1/23/2019.
Filed Date: 2/22/19.
Accession Number: 20190222–5036.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1100–000.
Applicants: SEPV Mojave West, LLC.
Description: Baseline eTariff Filing: SFA to be effective 2/23/2019.
Filed Date: 2/22/19.
Accession Number: 20190222–5073.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1101–000.
Applicants: Ontario Power Generation Energy Trading, Inc.
Description: § 205(d) Rate Filing: OPGET Market-Based Rate Tariff Filing to be effective 2/23/2019.
Filed Date: 2/22/19.
Accession Number: 20190222–5093.
Comments Due: 5 p.m. ET 3/15/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 22, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–03737 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL19–48–000]

Notice of Filing: Prairie Power, Inc.

Take notice that on February 22, 2019, Prairie Power, Inc. filed a proposed revenue requirement filing for reactive supply and voltage control service for its Alsey 6 Peaking Power Facility, under Midcontinent Independent Transmission System Operator Inc. Tariff Schedule 2.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the eLibrary link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on March 15, 2019.

Dated: February 25, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03758 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER19–716–001.
Applicants: PacifiCorp.

Description: Tariff Amendment: ESM Construction Agreement—Milford (update) to be effective 12/20/2018.
Filed Date: 2/25/19.
Accession Number: 20190225–5090.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–749–001.
Applicants: PacifiCorp.
Description: Tariff Amendment: ESM Construction Agreement—Sigurd (update) to be effective 12/20/2018.
Filed Date: 2/25/19.
Accession Number: 20190225–5088.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1115–000.
Applicants: AEP Texas Inc.
Description: § 205(d) Rate Filing: AEPTX-Maverick County WC&ID No.1 Interconnection Agreement 1st Amd & Restated to be effective 2/1/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5065.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1116–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA, SA No. 5284; Queue No. AD2–027 to be effective 1/26/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5071.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1117–000.
Applicants: Mirabito Power & Gas, LLC.
Description: Baseline eTariff Filing: MPG_MBR initial_tariff to be effective 3/1/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5073.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1118–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–02–25_SA 3246 Certificate of Concurrence Entergy-Southern TIA to be effective 1/1/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5085.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1119–000.
Applicants: Wheelabrator Ridge Energy Inc.
Description: Tariff Cancellation: Notice of Cancellation to be effective 2/26/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5091.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1120–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Second Revised ISA No. 3064, Queue No. W4–009/X4–005/AD1–113 to be effective 1/26/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5102.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1121–000.
Applicants: Wabash Valley Power Association, Inc., Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–02–25_Rate Schedule 52_AMMO–ATXI–WVPA JPZ Revenue Allocation Agreement to be effective 6/1/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5104.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1122–000.
Applicants: Midcontinent Independent System Operator, Inc., Wabash Valley Power Association, Inc.
Description: § 205(d) Rate Filing: 2019–02–25_Revisions to Schs 7, 8, and 9 to add ATXI and WVPA to Zone 3B to be effective 6/1/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5105.
Comments Due: 5 p.m. ET 3/18/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 25, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–03738 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD19–13–000]

Notice of Technical Conference; Reliability Technical Conference

Take notice that the Federal Energy Regulatory Commission (Commission) will hold a Technical Conference on Thursday, June 27, 2019, from 9:00 a.m. to 5:00 p.m. This Commissioner-led conference will be held in the Commission Meeting Room at the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The purpose of the conference is to discuss policy issues related to the reliability of the Bulk-Power System. The Commission will issue an agenda at a later date in a supplemental notice.

The conference will be open for the public to attend. There is no fee for attendance. However, members of the public are encouraged to preregister online at: *http://www.ferc.gov/whats-new/registration/06-27-19-form.asp*.

Those wishing to be considered for participation in panel discussions should submit nominations no later than close of business on March 15, 2019 online at: *http://www.ferc.gov/whats-new/registration/06-27-19-speaker-form.asp*.

Information on this event will be posted on the Calendar of Events on the Commission's website, *http://www.ferc.gov,* prior to the event. The conference will also be webcast and transcribed. Anyone with internet access who desires to listen to this event can do so by navigating to the Calendar of Events at *http://www.ferc.gov* and locating this event in the Calendar. The event will contain a link to the webcast. The Capitol Connection provides technical support for webcasts and offers the option of listening to the meeting via phone-bridge for a fee. If you have any questions, visit *http://www.CapitolConnection.org* or call (703) 993–3100. Transcripts of the technical conference will be available for a fee from Ace-Federal Reporters, Inc. at (202) 347–3700.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations, please send an email to *accessibility@ferc.gov* or call toll free 1 (866) 208–3372 (voice) or (202) 502–8659 (TTY), or send a fax to (202) 208–2106 with the required accommodations.

For more information about this technical conference, please contact Lodie White (202) 502–8453, *Lodie.White@ferc.gov*. For information related to logistics, please contact Sarah McKinley at (202) 502–8368, *Sarah.Mckinley@ferc.gov*.

Dated: February 25, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03764 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR19–41–000.
Applicants: Altus Midstream Pipeline LP.
Description: Tariff filing per 284.123(b), (e)+(g): Revised Statement of Operating Conditions to be effective 2/14/2019;
Filed Date: 2/22/19.
Accession Number: 201902225029.
Comments Due: 5 p.m. ET 3/15/19.
284.123(g) Protests Due: 5 p.m. ET 4/23/19.

Docket Numbers: RP19–671–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Negotiate Rate Agreement-J Aron and Company to be effective 4/1/2019.
Filed Date: 2/20/19.
Accession Number: 20190220–5000.
Comments Due: 5 p.m. ET 3/4/19.

Docket Numbers: RP19–672–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement-Spire Marketing Inc. to be effective 4/1/2019.
Filed Date: 2/20/19.
Accession Number: 20190220–5001.
Comments Due: 5 p.m. ET 3/4/19.

Docket Numbers: RP19–673–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement-Mercuria Energy America to be effective 4/1/2019.
Filed Date: 2/20/19.
Accession Number: 20190220–5002.
Comments Due: 5 p.m. ET 3/4/19.

Docket Numbers: RP19–674–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Negotiated Rate Agreement-Wells Fargo Commodities to be effective 4/1/2019.
Filed Date: 2/20/19.
Accession Number: 20190220–5003.
Comments Due: 5 p.m. ET 3/4/19.

Docket Numbers: RP19–206–002.
Applicants: Mississippi Canyon Gas Pipeline, L.L.C.
Description: Compliance filing MCGP Further Extension to file Form 501–G.
Filed Date: 2/21/19.
Accession Number: 20190221–5265.
Comments Due: 5 p.m. ET 2/26/19.

Docket Numbers: RP19–675–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: Housekeeping Filing on 2–20–19 to be effective 3/23/2019.
Filed Date: 2/21/19.
Accession Number: 20190221–5000.
Comments Due: 5 p.m. ET 3/5/19.

Docket Numbers: RP19–676–000.
Applicants: Florida Gas Transmission Company, LLC.
Description: § 4(d) Rate Filing: Housekeeping—Original Volume 1–A on 2–20–19 to be effective 3/23/2019.
Filed Date: 2/21/19.
Accession Number: 20190221–5001.
Comments Due: 5 p.m. ET 3/5/19.

Docket Numbers: RP19–677–000.
Applicants: Elba Express Company, L.L.C.
Description: § 4(d) Rate Filing: Shell Negotiated Rate 4/1/19 to be effective 4/1/2019.
Filed Date: 2/21/19.
Accession Number: 20190221–5083.
Comments Due: 5 p.m. ET 3/5/19.

Docket Numbers: RP19–678–000.
Applicants: Empire Pipeline, Inc.
Description: Compliance filing Refund Report (Per Settlement in RP16–300).
Filed Date: 2/21/19.
Accession Number: 20190221–5117.
Comments Due: 5 p.m. ET 3/5/19.

Docket Numbers: RP19–679–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Feb2019 Cleanup Filing to be effective 3/23/2019.
Filed Date: 2/21/19.
Accession Number: 20190221–5150.
Comments Due: 5 p.m. ET 3/5/19.

Docket Numbers: RP19–680–000.
Applicants: Munich Re Trading LLC,Castleton Commodities Merchant Trading L.
Description: Joint Petition for Temporary Waivers of Capacity Release Regulations and Policies, et al. of Munich Re Trading LLC, et al.
Filed Date: 2/21/19.
Accession Number: 20190221–5151.
Comments Due: 5 p.m. ET 2/28/19.

Docket Numbers: RP19–681–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20190221 Negotiated Rate to be effective 2/21/2019.
Filed Date: 2/21/19.
Accession Number: 20190221–5163.
Comments Due: 5 p.m. ET 3/5/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 22, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–03741 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2413–124]

Georgia Power Company Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Preliminary Terms and Conditions, and Preliminary Fishway Prescriptions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.
b. *Project No.:* 2413–124.
c. *Date filed:* May 31, 2018.
d. *Applicant:* Georgia Power Company (Georgia Power).
e. *Name of Project:* Wallace Dam Pumped Storage Project (Wallace Dam Project).
f. *Location:* The existing project is located on the Oconee River, in Hancock, Putnam, Green, and Morgan Counties, Georgia. The project occupies about 493.7 acres of federal land administered by the U.S. Forest Service.
g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)–825(r).
h. *Applicant Contact:* Courtenay R. O'Mara, P.E., Wallace Dam Hydro Relicensing Manager, Southern Company Generation, BIN 10193, 241 Ralph McGill Blvd. NE, Atlanta, GA 30308–3374; (404) 506–7219; *cromara@southernco.com.*

i. *FERC Contact:* Allan Creamer at (202) 502–8365, or at *allan.creamer@ferc.gov.*

j. *Deadline for filing motions to intervene and protests, comments, recommendations, preliminary terms and conditions, and preliminary prescriptions:* 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2413–124.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. *The Wallace Dam Project consists of:* (1) A 2,395-foot-long, 120-foot-high dam, consisting of (i) a 347-foot-long west earth embankment, (ii) a 300-foot-long west concrete non-overflow section, (iii) a 266-foot-long concrete spillway with five Tainter gates, each 48 feet high by 42 feet wide with a total discharge capacity of 35,000 cubic feet per second (cfs), (iv) a 531.4-foot-long powerhouse intake section, protected by trashracks having a clear bar spacing of 9.5 to 10.5 inches and leading to six penstocks with a maximum diameter of 25.5 feet, (v) a 226-foot-long east concrete non-overflow section, (vi) a 725-foot-long east earth embankment, and (vii) two saddle dikes, located east of the dam, totaling about 900 feet in length; (2) an 18,188-acre reservoir (Lake Oconee) at an elevation of 435.0 feet Plant Datum (where Plant Datum equals mean sea level (NAVD88) minus 0.20 feet); (3) a powerhouse integral with the dam that contains six turbine/generator units (two conventional generating units and four reversible pump units, with a total installed capacity of 321.3 megawatts; (4) a 20,000-foot-long tailrace that flows into Lake Sinclair, which serves as the lower reservoir for the Wallace Dam Project; (5) transmission facilities that consist of (i) 13.8-kilovolt (kV) generator leads, (ii) two 13.8/230-kV step-up transformers, (iii) a 230-kV substation, and (iv) a 15.67-mile-long transmission line that extends from Wallace Dam west to a switching station near Eatonton, Georgia; and (6) appurtenant facilities.

The Wallace Dam Project is a pumped storage project, generating 390,083 megawatt-hours of electricity annually. Water for generation at Wallace Dam comes from inflow, plus storage in Lake Oconee. The project generates during peak power demand hours to meet the electrical system demand. Water that is not used for generation at the downstream Sinclair Project FERC No. 1951, remains in Lake Sinclair for a few hours before being pumped back into Lake Oconee. Pumpback operation occurs at night, when electrical system demand is low (off-peak hours). For normal day-to-day operation, Lake Oconee fluctuates between elevations 435.0 and 433.5 feet Plant Datum, resulting in an average daily fluctuation of 1.5 feet. The Wallace Dam Project discharges directly into Lake Sinclair, with no intervening riverine or bypassed reach flows. Generation typically is the highest during the summer months, where Wallace Dam generates for about 7 to 8 hours during the afternoon peak demand period. During the fall and winter months, generation typically lasts 5 to 6 hours.

During drought periods, the Wallace Dam Project supports the minimum flow requirements of the downstream Sinclair Project. When the Sinclair Project's calculated inflow drops below its minimum flow requirement of 250 cfs, water is released from Lake Oconee to maintain the elevation of Lake Sinclair at the minimum level necessary for safe pumpback operation at Wallace Dam, which is 338.2 feet Plant Datum.

m. A copy of the application is available for review at the Commission in the Public Reference Room, or may be viewed on the Commission's website at *http://www.ferc.gov,* using the eLibrary link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on, or before, the specified deadline date for the particular application.

All filings must: (1) Bear in all capital letters the title PROTEST, MOTION TO INTERVENE, COMMENTS, REPLY COMMENTS, RECOMMENDATIONS, PRELIMINARY TERMS AND CONDITIONS, OR PRELIMINARY FISHWAY PRESCRIPTIONS; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, preliminary terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

o. *Procedural schedule:* The application will be processed according to the following revised Hydro Licensing Schedule. Further revisions to the schedule will be made as appropriate.

Milestone	Target date
Filing comments, recommendations, preliminary terms and conditions, and preliminary fishway prescriptions	April 2019.
Commission issues EA	October 2019.
Comments on EA	November 2019.
Filing modified terms and conditions	January 2020.

p. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of this notice.

q. *A license applicant must file, no later than 60 days following the date of issuance of the notice of acceptance and ready for environmental analysis provided for in 5.22:* (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

Dated: February 22, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03763 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC19–60–000.
Applicants: NedPower Mount Storm LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of NedPower Mount Storm, LLC.
Filed Date: 2/22/19.
Accession Number: 20190222–5195.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: EC19–61–000.
Applicants: Apple Blossom Wind, LLC, Black Oak Wind, LLC, Cedar Creek II, LLC, Flat Ridge 2 Wind Energy LLC, Fowler Ridge II Wind Farm LLC, Mehoopany Wind Energy LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Apple Blossom Wind, LLC, et al.
Filed Date: 2/22/19.
Accession Number: 20190222–5200.
Comments Due: 5 p.m. ET 3/15/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–2342–003.
Applicants: GridLiance Heartland LLC.
Description: Compliance filing: GridLiance Heartland LLC—ER18–2342 Compliance Filing to be effective N/A.
Filed Date: 2/22/19.
Accession Number: 20190222–5157.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1102–000.
Applicants: NextEra Energy Transmission West, LLC.
Description: § 205(d) Rate Filing: Revised Formula Rate Implementation Protocols to be effective 4/24/2019.
Filed Date: 2/22/19.
Accession Number: 20190222–5102.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1103–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–02–22 Attachment X revisions for Hybrid Interconnection to be effective 4/24/2019.
Filed Date: 2/22/19.
Accession Number: 20190222–5122.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1104–000.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Cancellation: Notice of Cancellation of ISA/SA No. 3986, Queue No. W3–099 to be effective 9/10/2018.
Filed Date: 2/22/19.
Accession Number: 20190222–5126.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1105–000.
Applicants: Central Maine Power Company.
Description: § 205(d) Rate Filing: Schedule 20A Service Agreements with Brookfield Energy Marketing LP (85 MW) to be effective 1/1/2020.
Filed Date: 2/22/19.
Accession Number: 20190222–5132.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1106–000.
Applicants: The United Illuminating Company.
Description: § 205(d) Rate Filing: Schedule 20A Service Agreements with Brookfield Energy Marketing LP (1 MW) to be effective 1/1/2020.
Filed Date: 2/22/19.
Accession Number: 20190222–5133.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1107–000.
Applicants: The United Illuminating Company.
Description: § 205(d) Rate Filing: Schedule 20A Service Agreements with Brookfield Energy Marketing LP (32 MW) to be effective 9/1/2020.
Filed Date: 2/22/19.
Accession Number: 20190222–5134.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1108–000.
Applicants: Citigroup Commodities Canada ULC.
Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 5/1/2019.
Filed Date: 2/22/19.
Accession Number: 20190222–5158.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1109–000.
Applicants: Windhub Solar A, LLC.
Description: Baseline eTariff Filing: Certificate of Concurrence to Co-Tenancy and Shared Facilities Agreement to be effective 2/25/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5000.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1110–000.
Applicants: Windhub Solar B, LLC.
Description: Baseline eTariff Filing: Certificate of Concurrence to Co-Tenancy and Shared Facilities Agreement to be effective 2/25/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5001.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1111–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3481 AEP and AECI Attachment AO to be effective 5/1/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5016.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1112–000.
Applicants: Flat Ridge 2 Wind Energy LLC, Fowler Ridge II Wind Farm LLC, Southwestern Electric Power Company, Indiana Michigan Power Company, Ohio Power Company.
Description: Request for Authorization to Make Affiliate Transactions of Flat Ridge 2 Wind Energy LLC, et al.
Filed Date: 2/22/19.
Accession Number: 20190222–5194.
Comments Due: 5 p.m. ET 3/15/19.

Docket Numbers: ER19–1113–000.
Applicants: Southwestern Public Service Company.
Description: § 205(d) Rate Filing: SPS–GSEC–LYNGR–IA-Thunderhead-708–0.0.0 to be effective 4/27/2019.

Filed Date: 2/25/19.
Accession Number: 20190225–5050.
Comments Due: 5 p.m. ET 3/18/19.
Docket Numbers: ER19–1114–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1910R15 Southwestern Public Service Company NITSA NOA to be effective 2/1/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5051.
Comments Due: 5 p.m. ET 3/18/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 25, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–03740 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Public Meetings Soliciting Comments on the Draft Environmental Impact Statement for the Don Pedro and La Grange Projects

Turlock Irrigation District	Project No. 2299–082.
Modesto Irrigation District	Project No. 14581–002.

On February 11, 2019, the Commission issued a Notice of Availability of the Draft Environmental Impact Statement for the Don Pedro and La Grange Projects. The draft EIS documents the views of governmental agencies, non-governmental organizations, affected Indian tribes, the public, the license applicants, and Commission staff. All written comments must be filed by April 12, 2019, and should reference Project No. 2299–082 and Project No. 14581–002. More information on filing comments can be found in the letter at the front of the draft EIS or on the Commission's website at *http://www.ferc.gov/docs-filing/efiling.asp.* Although the Commission strongly encourages electronic filing, documents may also be paper-filed.

In addition to or in lieu of sending written comments, you are invited to attend public meetings that will be held to receive comments on the draft EIS. The daytime meeting will focus on resource agency, Indian tribes, and non-governmental organization comments, while the evening meeting is primarily for receiving input from the public. All interested individuals and entities are invited to attend one or both of the public meetings. The time and location of the meetings are as follows:

Date: Tuesday, March 26, 2019.

Time: Daytime meeting—1–4 p.m. Pacific Daylight Time evening meeting—7–9 p.m. Pacific Daylight Time.

Place: Double Tree Hotel.

Address: 1150 Ninth Street, Modesto, CA 95354.

At this meeting, resource agency personnel and other interested persons will have the opportunity to provide oral and written comments and recommendations regarding the draft EIS. The meeting will be recorded by a court reporter, and all statements (verbal and written) will become part of the Commission's public record for the project. This meeting is posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

For further information, contact Jim Hastreiter at (503) 552–2760 or at *james.hastreiter@ferc.gov.*

Dated: February 25, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03759 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL19–47–000]

Notice of Complaint: Independent Market Monitor for PJM v. PJM Interconnection, LLC

Take notice that on February 21, 2019, pursuant to Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules and Practice and Procedure, 18 CFR 385.206 (2018), Monitoring Analytics, LLC, acting in its capacity as the Independent Market Monitor for PJM (Complainant) filed a formal complaint against PJM Interconnection, L.L.C. (Respondent) requesting that the Commission direct Respondent to revise the expected number of Performance Assessment Intervals (PAI) used to set the default Market Seller Offer Cap in Reliability Pricing Model (RPM) auctions to a level consistent with a reasonable and supportable expectation of PAI, as more fully explained in the complaint.

The Complainant states that copies of the complaint were served on representatives of the Respondent.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the eLibrary link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on March 13, 2019.

Dated: February 25, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03766 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD19–6–000]

Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene: City and County of Denver, Colorado

On February 19, 2019, as supplemented on February 25, 2019, the City and County of Denver, Colorado, filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA). The proposed Northwater Treatment Plant Hydropower Facility Project would have a total installed capacity of up to 950 kilowatts (kW), and would be located within the currently unconstructed Headworks Building of the Northwater Treatment Plant near Golden in Jefferson County, Colorado.

Applicant Contact: Peter McCormick, NTP Design Manager, 1600 W 12th Ave, Denver, Colorado 80204, Phone No. (303) 628–6084, Email: *peter.mccormick@denverwater.org*.

FERC Contact: Christopher Chaney, Phone No. (202) 502–6778, Email: *christopher.chaney@ferc.gov*.

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) One 450-kW turbine-generator unit, with a second up to 500-kW turbine-generator unit planned in the future, and (2) appurtenant facilities. The proposed project would have an estimated annual generation of up to 2,600 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A)	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar manmade water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i)	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii)	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii)	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: The proposed Northwater Treatment Plant Hydropower Facility Project will not interfere with the primary purpose of the conduit, which is to transport water for municipal use. Therefore, based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 30 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY or MOTION TO INTERVENE, as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov*, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE, Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the eLibrary link. Enter the docket number (*i.e.,* CD19–6) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659.

Dated: February 26, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03760 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2018).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER19–1108–000]

Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization: Citigroup Commodities Canada ULC

This is a supplemental notice in the above-referenced Citigroup Commodities Canada ULC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is March 18, 2019.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 25, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–03745 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC19–27–001.
Applicants: IIF US Holding LP.
Description: Informational Report of IIF US Holding LP, on behalf of its Public Utility Subsidiaries, et al.
Filed Date: 2/22/19.
Accession Number: 20190222–5103.
Comments Due: 5 p.m. ET 3/15/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–1267–005.
Applicants: GridLiance High Plains LLC.
Description: Compliance filing: GridLiance High Plains LLC Clean-up Tariff Revisions ER18–1267 to be effective 3/31/2018.
Filed Date: 2/26/19.
Accession Number: 20190226–5134.
Comments Due: 5 p.m. ET 3/19/19.

Docket Numbers: ER19–605–001.
Applicants: Republic Transmission, LLC.
Description: Tariff Amendment: Republic Transmission, LLC Deficiency Filing ER19–605–000 to be effective 2/26/2019.
Filed Date: 2/26/19.
Accession Number: 20190226–5110.
Comments Due: 5 p.m. ET 3/19/19.

Docket Numbers: ER19–1124–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–02–25_Revisions to Att. FF and FF–7 to Expand and Clarify Cost Allocation to be effective 6/25/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5172.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1125–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2019–02–25_Revisions to the TOA to Expand and Clarify Cost Allocation to be effective 6/25/2019.
Filed Date: 2/25/19.
Accession Number: 20190225–5173.
Comments Due: 5 p.m. ET 3/18/19.

Docket Numbers: ER19–1127–000.
Applicants: Calpine King City Cogen, LLC.
Description: Baseline eTariff Filing: Application for MBR Authorization and Request for Waivers and Blanket Approvals to be effective 4/1/2019.
Filed Date: 2/26/19.
Accession Number: 20190226–5063.
Comments Due: 5 p.m. ET 3/19/19.

Docket Numbers: ER19–1128–000.
Applicants: Rush Springs Energy Storage, LLC.
Description: Baseline eTariff Filing: Rush Springs Energy Storage, LLC Application for Market-Based Rates to be effective 5/1/2019.
Filed Date: 2/26/19.
Accession Number: 20190226–5132.
Comments Due: 5 p.m. ET 3/19/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 26, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–03756 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10674–017]

Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments: Kaukauna Utilities

Take notice that the following hydroelectric application has been filed

with the Commission and is available for public inspection.

a. *Type of Application:* New Major license.

b. *Project No.:* 10674–017.

c. *Date filed:* February 14, 2019.

d. *Applicant:* Kaukauna Utilities.

e. *Name of Project:* Kimberly Hydroelectric Project.

f. *Location:* The Kimberly Project is located at the U.S. Army Corps of Engineers' (Corps) Cedars Dam on the Lower Fox River in the Village of Kimberly in Outagamie County, Wisconsin. The project does not occupy federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Mike Pedersen, Manager of Generation and Operations, Kaukauna Utilities, 777 Island Street, P.O. Box 1777, Kaukauna, WI 54130–7077, (902) 766–05721.

i. *FERC Contact:* Colleen Corballis, (202) 502–8598, *colleen.corballis@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: April 15, 2019.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–10674–017.

m. The application is not ready for environmental analysis at this time.

n. *The project consists of:* (1) A 161-foot-long, 43-foot-wide, 61-foot-high reinforced concrete and brick masonry powerhouse located at the south abutment of Cedars Dam and containing three turbine-generator units each rated at 723 kilowatts for a total installed capacity of 2.170 megawatts; (2) a 2.4 kilovolts (kV) to 34.5 kV step-up transformer; and (3) appurtenant facilities. The project is directly connected to a 34.5 kV local distribution line which is not part of the project. The average annual generation was 12,324,827 kilowatt-hours for the period 2011 to 2017.

o. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural schedule and final amendments:* The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary)—April 2019
Request Additional Information (if necessary)—April 2019
Issue Scoping Document 1 for comments—August 2019
Request Additional Information (if necessary)—October 2019
Issue Scoping Document 2 (if necessary)—November 2019
Issue Notice of Ready for Environmental Analysis—November 2019
Commission issues EA—May 2020

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: February 22, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03767 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD19–5–000]

Coleman Hydro LLC, Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On February 12, 2019, Coleman Hydro LLC filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA). The proposed LTC Hydro Project would have a total installed capacity of 750 kilowatts (kW), and would be located at the termination point of the existing 24-inch diameter LTC-Tyler pipeline near Leadore in Lemhi County, Idaho.

Applicant Contact: Nicholas E. Josten, 2742 St. Charles Ave., Idaho Falls, ID 83404, Phone No. (208) 528–6152, Email: *gsense@cableone.net.*

FERC Contact: Christopher Chaney, Phone No. (202) 502–6778, Email: *christopher.chaney@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) An approximately 20-foot by 24-foot powerhouse containing a single 750-kW turbine-generator, and (2) appurtenant facilities. The proposed project would have an estimated annual generation of up to 2,200 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all of the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A)	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar man-made water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i)	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii)	The facility has an installed capacity that does not exceed 5 megawatts	Y
FPA 30(a)(3)(C)(iii)	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: The proposed LTC Hydro Project will not interfere with the primary purpose of the conduit, which is to transport water for irrigation. Therefore, based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 30 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY or MOTION TO INTERVENE, as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Locations of Notice of Intent: Copies of the notice of intent can be obtained directly from the applicant or such copies can be viewed and reproduced at the Commission in its Public Reference Room, Room 2A, 888 First Street NE, Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the eLibrary link. Enter the docket number (*i.e.,* CD19–5) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: February 22, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03761 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

[1] 18 CFR 385.2001–2005 (2018).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP19–688–000.

Applicants: East Tennessee Natural Gas, LLC.

Description: § 4(d) Rate Filing: ARP 410502 Permanent Release to Summit 410659 to be effective 3/1/2019.

Filed Date: 2/25/19.

Accession Number: 20190225–5038.

Comments Due: 5 p.m. ET 3/11/19.

Docket Numbers: RP19–689–000.

Applicants: SG Resources Mississippi, L.L.C.

Description: § 4(d) Rate Filing: SG Resources Mississippi. L.L.C.—Revisions to FERC Gas Tariff to be effective 3/25/2019.

Filed Date: 2/25/19.

Accession Number: 20190225–5057.

Comments Due: 5 p.m. ET 3/11/19.

Docket Numbers: RP19–690–000.

Applicants: Black Marlin Pipeline LLC.

Description: § 4(d) Rate Filing: 2019 Black Marlin name change to be effective 3/27/2019.

Filed Date: 2/25/19.

Accession Number: 20190225–5103.

Comments Due: 5 p.m. ET 3/11/19.

Docket Numbers: RP19–691–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate—Yankee to Direct Energy 798785 to be effective 2/26/2019.

Filed Date: 2/25/19.

Accession Number: 20190225–5117.

Comments Due: 5 p.m. ET 3/11/19.

Docket Numbers: RP19–692–000.

Applicants: Black Hills Shoshone Pipeline, LLC.

Description: Annual Adjustment of Lost and Unaccounted for Gas Percentage of Black Hills Shoshone Pipeline, LLC under RP19–692.

Filed Date: 2/25/19.

Accession Number: 20190225–5185.

Comments Due: 5 p.m. ET 3/11/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's

Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 26, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–03757 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP19–641–001.

Applicants: Dominion Energy Questar Pipeline, LLC.

Description: Tariff Amendment: 2019 Cleanup, Amended Filing to be effective 3/10/2019.

Filed Date: 2/21/19.

Accession Number: 20190221–5166.

Comments Due: 5 p.m. ET 3/5/19.

Docket Numbers: RP19–642–001.

Applicants: Dominion Energy Overthrust Pipeline, LLC.

Description: Tariff Amendment: 2019 Cleanup, Amended Filing to be effective 3/10/2019.

Filed Date: 2/21/19.

Accession Number: 20190221–5167.

Comments Due: 5 p.m. ET 3/5/19.

Docket Numbers: RP19–682–000.

Applicants: East Tennessee Natural Gas, LLC.

Description: § 4(d) Rate Filing: ETNG 2019–02–22 Negotiated Rate Cleanup Filing to be effective 3/25/2019.

Filed Date: 2/22/19.

Accession Number: 20190222–5034.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: RP19–683–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Non-Conforming—St. James Supply to be effective 4/1/2019.

Filed Date: 2/22/19.

Accession Number: 20190222–5035.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: RP19–684–000.

Applicants: Clear Creek Storage Company, L.L.C.

Description: Tariff Cancellation: Cancellation of Clear Creek Storage Company, L.L.C. Tariff to be effective 2/22/2019.

Filed Date: 2/22/19.

Accession Number: 20190222–5059.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: RP19–685–000.

Applicants: Millennium Pipeline Company, L.L.C.

Description: Operational Transactions Report of Millennium Pipeline Company, LLC under RP19–685.

Filed Date: 2/22/19.

Accession Number: 20190222–5097.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: RP19–686–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate 2019–02–21 Amend BHS (3) to be effective 2/21/2019.

Filed Date: 2/22/19.

Accession Number: 20190222–5137.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: RP19–687–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate 2019–02–22 Amend (1) BHS DTE to be effective 2/22/2019.

Filed Date: 2/22/19.

Accession Number: 20190222–5156.

Comments Due: 5 p.m. ET 3/6/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 25, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–03744 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP19–86–000]

Notice of Request Under Blanket Authorization; Spire Storage West, LLC

Take notice that on February 13, 2019, Spire Storage West LLC (Spire Storage), 3773 Richmond Avenue, Suite 300, Houston, Texas 77046, filed an application under sections 157.205, 157.208 and 157.213 and Pursuant to 18 CFR 157.205, 157.208 and 157.213(b) and the blanket certificate issued to Spire Storage in Docket No. CP11–24–000, Spire Storage requests authorization Pursuant to 18 CFR 157.205, 157.208 and 157.213(b) and the blanket certificate granted in Docket No. CP11–24–000. to construct the Rock Pipeline, consisting of 10.1 miles of dual 20-inch pipeline, a new pipeline interconnection and appurtenant facilities at its natural gas storage facilities in Uinta County, Wyoming.

Spire Storage states that the Rock Pipeline will allow Spire Storage to make enhanced storage service options available to its customers. The proposed pipeline and measurement facilities will provide Spire Storage's two storage facilities access to a new high capacity bi-directional interconnect with Kern River Gas Transmission Company's mainline, will establish a robust link between the two storage facilities and will afford enhanced access to interconnections with other interstate natural gas pipelines.

The filing may also be viewed on the web at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Questions regarding this application should be directed to James F. Bowe, Jr., King & Spalding LLP, 1700 Pennsylvania Avenue NW, Suite 200, Washington, DC 20006, 202–626–9601 (phone) 202–626–3737 (fax), *jbowe@kslaw.com.*

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the

time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenter will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on April 26, 2019.

Dated: February 25, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–03765 Filed 3–1–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2007–1196; FRL–9990–29–OAR]

Recent Postings of Broadly Applicable Alternative Test Methods

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces the broadly applicable alternative test method approval decisions that the Environmental Protection Agency (EPA) has made under and in support of New Source Performance Standards (NSPS) and the National Emission Standards for Hazardous Air Pollutants (NESHAP) between January 1, 2018, and December 31, 2018.

FOR FURTHER INFORMATION CONTACT: An electronic copy of each alternative test method approval document is available at *https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods.* For questions about this notice, contact Mrs. Lula H. Melton, Air Quality Assessment Division, Office of Air Quality Planning and Standards (E143–02), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–2910; fax number: (919) 541–0516; email address: *melton.lula@epa.gov.* For technical questions about individual alternative test method decisions, refer to the contact person identified in the individual approval document(s).

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to me?

This notice will be of interest to entities regulated under 40 Code of Federal Regulations (CFR) parts 60, 61, and 63; state, local, and tribal agencies; and the EPA Regional offices responsible for implementation and enforcement of regulations under 40 CFR parts 60, 61, and 63.

B. How can I get copies of this information?

You may access copies of the broadly applicable alternative test method approval documents at *https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods.*

II. Background

This notice identifies broadly applicable alternative test method approval decisions made by the EPA in 2018 under the NSPS, 40 CFR part 60 and the NESHAP programs, and 40 CFR parts 61 and 63 (see Table 1). Source owners and operators may voluntarily use these broadly applicable alternative test methods in lieu of otherwise specified reference test methods. Use of these broadly applicable alternative test methods does not change the applicable emission standards.

The Administrator has the authority to approve the use of alternative test methods for compliance with requirements under 40 CFR parts 60, 61, and 63. This authority is found in sections 60.8(b)(3), 61.13(h)(1)(ii), and 63.7(e)(2)(ii). Additional and similar authority can be found in 40 CFR 65.158(a)(2). The criteria for approval and procedures for submission and review of broadly applicable alternative test methods are explained in a previous **Federal Register** notice published at 72 FR 4257 (January 30, 2007) and located at *https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods.* As explained in this notice, we will announce approvals for broadly applicable alternative test methods at *https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods* and publish an annual notice that summarizes approvals for broadly applicable alternative test methods during the preceding year.

As also explained in the January 30, 2007 notice, our approval decisions involve thorough technical reviews of numerous source-specific requests for alternatives and modifications to test methods and procedures. Based on these reviews, we have often found that these modifications or alternatives would be equally valid and appropriate to apply to other sources within a particular class, category, or subcategory. Consequently, we have concluded that where a method modification or an alternative method is clearly broadly applicable to a class, category, or subcategory of sources, it is both equitable and efficient to approve its use for all appropriate sources and situations at the same time.

Use of approved alternative test methods are not mandatory but rather permissive. Sources are not required to employ such a method but may choose to do so in appropriate circumstances. As per section 63.7(f)(5), however, a source owner or operator electing to use an alternative method for 40 CFR part

63 standards must continue to use the alternative method until otherwise authorized. Source owners or operators should, therefore, review the specific broadly applicable alternative method approval decision at *https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods* before electing to employ any alternative method.

III. Approved Alternative Test Methods and Modifications to Test Methods

This notice specifies ten broadly applicable alternative test methods that the EPA approved between January 1, 2018, and December 1, 2018. The alternative method decision letter/memo number, the reference method affected, sources allowed to use this alternative, and the modification or alternative method allowed are summarized in Table 1 of this notice. A summary of approval documents was previously made available on our Technology Transfer Network between January 1, 2018, and December 31, 2018. For more detailed information, please refer to the complete copies of these approval documents available at *https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods.*

As also explained in our January 30, 2007 notice, we will revisit approvals of alternative test methods in response to written requests or objections indicating that a particular approved alternative test method either should not be broadly applicable or that its use should in some way be limited. Any objection to a broadly applicable alternative test method, as well as the resolution of that objection, will be announced at *https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods* and in a subsequent **Federal Register** notice. If we decide to retract a broadly applicable test method, we will likely consider the need for an appropriate transition period for users either to request case-by-case approval or to transition to an approved method.

Dated: January 29, 2019.

Richard A. Wayland,

Director, Air Quality Assessment Division.

TABLE 1—APPROVED ALTERNATIVE TEST METHODS AND MODIFICATIONS TO TEST METHODS REFERENCED IN OR PUBLISHED UNDER APPENDICES IN 40 CFR PARTS 60, 61, AND 63 POSTED BETWEEN JANUARY 2018 AND DECEMBER 2018

Alternative method decision letter/memo No.	As an alternative or modification to . . .	For . . .	You may . . .
ATL–123	Method 3A, Method 3B, or ANSI/ASME PTC 19.10–1981.	Sources subject to 40 CFR part 63, subpart UUUUU—National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-Fired Electric Utility Steam Generating Units.	Use procedures specified in the Appendix of the Agency's approval letter dated February 13, 2018, and the modifications specified in the Agency's approval letter dated March 6, 2018.
ALT–124	40 CFR 63.670 and 63.671	Sources subject to 40 CFR part 63, subpart CC—National Emission Standards for Hazardous Air Pollutants from Petroleum Refineries.	Use continuous process mass spectrometry in lieu of continuous gas chromatography to measure Net Heating Value (NHV_{VG}) using the measurement approach and requirements specified in the Agency's approval letter dated February 5, 2018.
ALT–125	40 CFR 60.534	Sources subject to 40 CFR part 60, subpart AAA—Standards of Performance for New Residential Wood Heaters.	Use ASTM E3053–17 and ASTM E2515–11 both with the change(s) specified in the Agency's approval letter dated February 28, 2018, and Canadian Standards Administration (CSA) Method CSA–B415.1–10.
ALT–126	ASTM E2515–11, section 10.2.2	Sources subject to 40 CFR part 60, subpart AAA—Standards of Performance for New Residential Wood Heaters and 40 CFR part 60, subpart QQQQ—New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces.	Use the procedure specified in the Agency's approval letter dated March 6, 2018, Method 5, sections 8.7, 11.2.1 and 11.2.2, and ASTM E2515–11.
ALT–127	40 CFR 60.534	Sources subject to 40 CFR part 60, subpart AAA—Standards of Performance for New Residential Wood Heaters.	Use ASTM E3053–17 and ASTM E2515–11 both with the change(s) specified in the Agency's approval letter dated April 13, 2018, and Canadian Standards Administration (CSA) Method CSA–B415.1–10.
ALT–128	Method 25—Determination of Total Gaseous Nonmethane Organic Emissions as Carbon.	Sources subject to 40 CFR parts 60 and 63, subparts specified in the Agency's approval letter dated April 18, 2018.	Use an alternative filter, filter holder, and filter heater box as specified in the Agency's approval letter dated April 18, 2018.
ALT–129	Method 26—Determination of Hydrogen Halide and Halogen Emissions From Stationary Sources Non-Isokinetic Method and Method 26A—Determination of Hydrogen Halide and Halogen Emissions From Stationary Sources Isokinetic Method.	Sources subject to 40 CFR part 63, subpart UUUUU—National Emission Standards for Hazardous Air Pollutants: Coal- and Oil-fired Electric Utility Steam Generating Units.	Use sorbent trap method (Other Test Method (OTM)-40) for HCl emissions from the specific coal-fired electric utility steam generating units and the provisos in the Agency's approval letter dated May 30, 2018.

TABLE 1—APPROVED ALTERNATIVE TEST METHODS AND MODIFICATIONS TO TEST METHODS REFERENCED IN OR PUBLISHED UNDER APPENDICES IN 40 CFR PARTS 60, 61, AND 63 POSTED BETWEEN JANUARY 2018 AND DECEMBER 2018—Continued

Alternative method decision letter/memo No.	As an alternative or modification to . . .	For . . .	You may . . .
ALT–130	SW–846 Method 8260B	Sources subject to 40 CFR part 63, subpart HHHHHHH—Polyvinyl Chloride and Copolymers Production: National Emission Standards for Hazardous Air Pollutants (NESHAP).	SW–846 Method 8260C and SW–846 Method 8260D with the performance criteria specified in the Agency's approval letter dated October 17, 2018.
ALT–131	Quality assurance procedures in Performance Specification 9 and 40 CFR 63.671(e)(2) and (e)(3).	Sources subject to 40 CFR part 63, subpart CC—National Emission Standards for Hazardous Air Pollutants from Petroleum Refineries.	Use the alternative quality assurance procedures specified in the Agency's approval letter dated December 13, 2018.
ALT–132	40 CFR 63.1350(k)(2)(ii) and (iii)	Sources subject to 40 CFR part 63, subpart LLL—National Emission Standards for Hazardous Air Pollutants from the Portland Cement Manufacturing Industry.	Use the alternative procedure for "above span" mercury calibrations only as specified in the Agency's approval letter dated December 18, 2018. This alternative procedure replaces ALT–120, which expired January 1, 2019.

Source owners or operators should review the specific broadly applicable alternative method approval letter at *https://www.epa.gov/emc/broadly-applicable-approved-alternative-test-methods* before electing to employ it.

[FR Doc. 2019–03850 Filed 3–1–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2014–0031; FRL–9988–44–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NSPS for Petroleum Dry Cleaners (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), NSPS for Petroleum Dry Cleaners (EPA ICR Number 0997.12, OMB Control Number 2060–0079), to the Office of Management and Budget (OMB), for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through March 31, 2019. Public comments were previously requested, via the **Federal Register**, on June 29, 2017 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before April 3, 2019.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2014–0031, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–2970; fax number: (202) 564–0050; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: The New Source Performance Standards (NSPS) for Petroleum Dry Cleaners (40 CFR part 60, subpart JJJ) apply to the following existing and new facilities located at a petroleum dry cleaning plant with a total manufacturers' rated dryer capacity equal to or greater than 38 kilograms (84 pounds): Petroleum solvent dry cleaning dryers, washers, filters, stills, and settling tanks. In general, NSPS standards require initial notification reports, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are generally considered essential in determining compliance, and are required of all affected facilities subject to NSPS. For this source category, only recordkeeping and initial notifications and reports are considered essential in determining compliance with 40 CFR part 60, subpart JJJ.

Form Numbers: None.

Respondents/affected entities: Petroleum dry cleaners.

Respondent's obligation to respond: Mandatory (40 CFR part 60, subpart JJJ).

Estimated number of respondents: 20 (total).

Frequency of response: Initially.

Total estimated burden: 1,850 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $202,000 (per year), which includes $0 for annualized capital/startup and/or operation & maintenance costs.

Changes in the Estimates: There is no change in the burden in this ICR compared to the previous ICR. This is due to two considerations: (1) The regulations have not changed over the past three years and are not anticipated to change over the next three years; and (2) the growth rate for the industry is estimated to remain the same as for the last ICR, so there is no significant change in the overall burden.

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2019–03778 Filed 3–1–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9989–26–Region 9]

Clean Air Act Prevention of Significant Deterioration Permit Issued to Tucson Electric Power for the Irvington Generating Station Project

Correction

In notice document 2019–01921, appearing on pages 3159 through 3160, in the issue of Monday, February 11, 2019, make the following correction:

On page 3159, in the third column, in the ''**DATES:**'' section, the text entry that reads ''April 12, 2019'' should read ''February 11, 2019''.

[FR Doc. C1–2019–01921 Filed 3–1–19; 8:45 am]

BILLING CODE 1301–00–D

EXPORT-IMPORT BANK

[Public Notice: 2019–6003]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995. The purpose of this collection is to gather information necessary to make a determination of eligibility of a transaction for EXIM assistance under its medium-term guarantee and insurance program.

DATES: Comments should be received on or before May 3, 2019 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *http://www.regulations.gov* (EIB 03–02) or by email to *Mia.Johnson@exim.gov* or by mail to Mia L. Johnson, Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571. The form can be viewed at: *http://www.exim.gov/sites/default/files/pub/pending/eib03–02_0.pdf.*

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 03–02 Application for Medium Term Insurance or Guarantee.

OMB Number: 3048–0014.

Type of Review: Renewal.

Need and Use: The purpose of this collection is to gather information necessary to make a determination of eligibility of a transaction for EXIM assistance under its medium-term guarantee and insurance program.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 400.

Estimated Time per Respondent: 2 hours.

Annual Burden Hours: 800 hours.

Frequency of Reporting or Use: As needed.

Government Expenses:

Reviewing Time per Year: 700 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $29,750 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $35,700.

Bassam Doughman,

IT Specialist.

[FR Doc. 2019–03804 Filed 3–1–19; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2018–3022]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Banks of the United States (EXIM), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995. This collection of information is necessary to determine eligibility of the applicant for EXIM assistance.

DATES: Comments must be received on or before April 3, 2019, to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* (EIB 92–36) or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW, Washington, DC 20038, Attn: OMB 3048–0016. The application tool can be reviewed at: *https://www.exim.gov/sites/default/files/pub/pending/eib92-36.pdf.*

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 92–36 Application for Issuing Bank Credit Limit (IBCL) Under Lender or Exporter-Held Policies.

OMB Number: 3048–0016.

Type of Review: Renewal.

Need and Use: This form is used by an insured exporter or lender (or broker acting on its behalf) in order to obtain approval for coverage of the repayment risk of an overseas bank. The information received allows EXIM staff to make a determination of the creditworthiness of the foreign bank and the underlying export sale for Ex-Im Bank assistance under its programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 600.

Estimated Time per Respondent: 1.2 hours.

Annual Burden Hours: 720 hours.

Frequency of Reporting of Use: As needed.

Government Expenses:

Reviewing Time per Year: 600 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $25,500 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $30,600.

Bassam Doughman,

IT Specialist.

[FR Doc. 2019–03802 Filed 3–1–19; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2019–6004]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995. This collection of information is necessary to determine eligibility of the applicant for EXIM assistance. The Application for Short-Term Multi-Buyer Export Credit Insurance Policy will be used to determine the eligibility of the applicant and the transaction for Export-Import Bank assistance under its insurance program. Export-Import Bank customers will be able to submit this form on paper or electronically.

DATES: Comments must be received on or before May 3, 2019 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* (EIB 92–50) or by email to *Mia.Johnson@exim.gov* or by mail to Mia L. Johnson, Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC 20571. The application tool can be reviewed at: *http://www.exim.gov/sites/default/files/pub/pending/eib92-50.pdf.*

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 92–50 Application for Short-Term Multi-Buyer Export Credit Insurance Policy.

OMB Number: 3048–0023.

Type of Review: Renewal.

Need and Use: The Application for Short-Term Multi-Buyer Export Credit Insurance Policy will be used to determine the eligibility of the applicant and the transaction for Export-Import Bank assistance under its insurance program.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 285.

Estimated Time per Respondent: 0.5 hours.

Annual Burden Hours: 143.

Frequency of Reporting of Use: As needed.

Government Reviewing Time per Year:

Reviewing Time per Year: 285 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $12,113 (time * wages).

Benefits and Overhead: 20%.

Total Government Cost: $14,535.

Bassam Doughman,

IT Specialist.

[FR Doc. 2019–03815 Filed 3–1–19; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act; Technological Advisory Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC) Technological Advisory Council will hold a meeting at the Federal Communications Commission.

DATES: Tuesday, March 26, 2019.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Michael Ha, Deputy Chief, Policy and Rules Division 202–418–2099; *michael.ha@fcc.gov.*

SUPPLEMENTARY INFORMATION: At the March 26th meeting, the FCC Technological Advisory Council will discuss final recommendations from the 2018 TAC Working Groups. The FCC will attempt to accommodate as many people as possible. However, admittance will be limited to seating availability. Meetings are also broadcast live with open captioning over the internet from the FCC Live web page at *http://www.fcc.gov/live/.* The public may submit written comments before the meeting to: Michael Ha, the FCC's Designated Federal Officer for Technological Advisory Council by email: *michael.ha@fcc.gov* or U.S. Postal Service Mail (Michael Ha, Federal Communications Commission, Room 2–A665, 445 12th Street SW, Washington, DC 20554). Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Office of Engineering and Technology at 202–418–2470 (voice), (202) 418–1944 (fax). Such requests should include a detailed description of the accommodation needed. In addition, please include your contact information. Please allow at least five days advance notice; last minute requests will be accepted, but may not be possible to fill.

Federal Communications Commission.

Julius Knapp,

Chief, Office of Engineering and Technology.

[FR Doc. 2019–03735 Filed 3–1–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Consolidated Holding Company Report of Equity Investments in Nonfinancial Companies and the Annual Report of Merchant Banking Investments Held for an Extended Period (FR Y–12 and FR Y–12A; OMB No. 7100–0300). The revisions to the FR Y–12 are applicable as of the March 31, 2019, reporting date, and the revisions to the FR Y–12A are applicable as of the December 31, 2019, reporting date.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Board may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Report title: Consolidated Holding Company Report of Equity Investments in Nonfinancial Companies, and Annual Report of Merchant Banking Investments Held for an Extended Period.

Agency form numbers: FR Y–12 and FR Y–12A.

OMB control number: 7100–0300.

Effective dates: The revisions to the FR Y–12 are applicable as of the March 31, 2019, reporting date, and the revisions to the FR Y–12A are applicable as of the December 31, 2019, reporting date.

Frequency: FR Y–12, quarterly or semiannually based on the reporting threshold criteria; FR Y–12A, annually.

Respondents: FR Y–12: Bank holding companies (BHCs), savings and loan holding companies (SLHCs), and U.S. intermediate holding companies (IHCs). FR Y–12A: Financial holding companies (FHCs) that hold merchant banking investments that are approaching the end of the holding periods permissible under the Board's Regulation Y.[1]

Number of respondents: FR Y–12, 27 quarterly and 5 semiannually; FR Y–12A, 439.

Estimated average hours per response: FR Y–12, 16.5 hours; FR Y–12A, 7.5 hours.

Estimated annual reporting hours: FR Y–12, 1,947 hours; FR Y–12A, 3,293 hours.

General description of report: The FR Y–12 collects information from certain domestic BHCs, SLHCs, and U.S. IHCs on their equity investments in nonfinancial companies. Respondents report the FR Y–12 either quarterly or semiannually based on the criteria in the reports. The FR Y–12A is filed annually by FHCs that hold merchant banking investments that are approaching the end of the holding periods permissible under the Board's Regulation Y.

Legal authorization and confidentiality: The FR Y–12 and FR Y–12A are mandatory and are authorized to be collected from BHCs and FHCs pursuant to section 5(c) of the Bank Holding Company Act (BHC Act) (12 U.S.C. 1844(c)(1)(A)); from SLHCs pursuant to section 10(b)(2) of the Home Owners Loan Act (HOLA) (12 U.S.C. 1467a(b)(2)), as amended by section 369(8) of the Dodd-Frank Wall Street and Consumer Protection Act (Dodd-Frank Act); and from IHCs pursuant to section 5(c) of the BHC Act, (12 U.S.C. 1844(c)(1)(A)), as well as pursuant to sections 102(a)(1) and 165 of the Dodd-Frank Act, (12 U.S.C. 5311(a)(1) and 5365),[2] and the Board's Regulation YY, 12 CFR 252.153(b)(2).

In addition, with respect to the FR Y–12A report, section 4(k)(7)(A) of the BHC Act, (12 U.S.C. 1843(k)(7)(A)), authorizes the Board and the Treasury Department to jointly develop implementing regulations governing merchant banking activities for purposes of section 4(k)(4)(H) of the BHC Act. Section 4(k)(4)(H) of the BHC Act, (12 U.S.C. 1843(k)(4)(H)), and subpart J of the Board's Regulation Y, (12 CFR 225.170 *et seq.*), authorize a BHC that has made an effective FHC election to acquire merchant banking investments that are not otherwise permissible for an FHC. Section 10(c)(2)(H) of the HOLA, as amended by section 606(b) of the Dodd-Frank Act, (12 U.S.C. 1467a(c)(2)(H)), and section 8(a) of the International Bank Act, (12 U.S.C. 3106(a)), extend certain authorities and requirements of the BHC Act to SLHCs and to foreign banks, respectively.

The Board does not consider information collected on the FR Y–12 report to be confidential, and the completed version of this report generally is made available to the public upon request. However, exemption 4 of the Freedom of Information Act (FOIA) provides an exemption from public disclosure for ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.'' (5 U.S.C. 552(b)(4)). Thus, if a respondent feels that disclosure of confidential commercial or financial information on the FR Y–12 report is reasonably likely to result in substantial harm to its competitive position under exemption 4 of the FOIA, the respondent may request confidential treatment for such information pursuant to the Board's Rules Regarding the Availability of Information, 12 CFR 261.15.

The Board generally considers the information collected on the FR Y–12A to be confidential under exemption 4 of the FOIA (5 U.S.C. 552(b)(4)). Information reported on the FR Y–12A is competitively sensitive and its release would likely result in substantial harm to the competitive position of an FHC or SLHC. In addition, if the FR Y–12A data is obtained as a part of an examination or supervision of a financial institution, this information may also be withheld pursuant to exemption 8 of the FOIA, which protects information contained in ''examination, operating, or condition reports'' obtained in the bank supervisory process (5 U.S.C. 552(b)(8)).

Current actions: On November 5, 2018, the Board invited comment on a proposal[3] to extend for three years, with revision, the FR Y–12 and FR Y–12A. The Board proposed to revise the FR Y–12 by requiring that dollar values be reported in thousands instead of millions, and by no longer requiring firms to report the fax number of the person to be contacted regarding a report submission. The Board proposed the following revisions to the FR Y–12A: (1) Requiring that dollar values be reported in thousands instead of millions, (2) adding an item for the holding period expiration date of the covered investment, (3) expanding the scope of the item where a respondent indicates its plan and schedule for disposition of its covered investment, (4) clarifying that the top-tier FHC should be the filer for each submitted report, (5) adding an item for the RSSD ID[4] of the direct holder of the covered investment, (6) clarifying that an FHC must continue to file the report until it ceases to hold the covered investment, (7) no longer requiring firms to report the fax number of the person to be contacted regarding a report submission, and (8) making minor clarifications throughout the instructions.

Detailed discussion of public comments: The commenter supported the collection of supervisory information through the FR Y–12 and FR Y–12A reports and did not contest the accuracy of the burden estimate. In addition, the commenter made three recommendations. The first recommendation was that the collected information should be notarized. Since the FR Y–12 and FR Y–12A currently require an attestation of truthfulness and accuracy by an executive officer,

[1] *See* 12 CFR 225.172(b)(4) and 225.173(c).

[2] Section 165(b)(2) of Title I of the Dodd-Frank Act, (12 U.S.C. 5365(b)(2)), refers to a ''foreign-based bank holding company.'' Section 102(a)(1) of the Dodd-Frank Act, (12 U.S.C. 5311(a)(1)), defines ''bank holding company'' for purposes of Title I of the Dodd-Frank Act to include foreign banking organizations that are treated as bank holding companies under section 8(a) of the International Banking Act, (12 U.S.C. 3106(a)). The Board has required, pursuant to section 165(b)(1)(B)(iv) of the Dodd-Frank Act, (12 U.S.C. 5365(b)(1)(B)(iv)), certain of the foreign banking organizations that are subject to section 165 of the Dodd-Frank Act to form U.S. IHCs. Accordingly, the parent foreign-based organization of a U.S. IHC is treated as a BHC for purposes of the BHC Act and section 165 of the Dodd-Frank Act. Because section 5(c) of the BHC Act authorizes the Board to require reports from subsidiaries of BHCs, section 5(c) provides additional authority to require U.S. IHCs to report the information contained in the FR Y–12 and FR Y–12A reports.

[3] *See* 83 FR 55366 (November 5, 2018).

[4] An RSSD ID is a unique identifier assigned to institutions by the Federal Reserve.

the Board believes this obviates the need for notarization. The second recommendation was to use a website for submissions to minimize burden. The Board currently allows submission of the FR Y–12 and FR Y–12A by mail or electronically via the Federal Reserve System's Reporting Central application, so the Board does not believe an additional electronic submission mechanism is necessary. The third recommendation was to ensure that respondents are aware of exactly which information must be reported, and the reasons that this information is required. Board staff has strived to draft instructions for the FR Y–12 and FR Y–12A reports that are as clear as possible and will continue to explore ways to increase the clarity of those instructions. The Board's public OMB supporting statements and **Federal Register** notices regarding the FR Y–12 and FR Y–12A reports explain that the information collected by the reports is necessary for the Board to carry out its responsibilities of supervising holding companies and maintaining U.S. financial stability.

The revisions to the FR Y–12 and FR Y–12A will be implemented as proposed.

Board of Governors of the Federal Reserve System, February 26, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–03776 Filed 3–1–19; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (''Act'') (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than March 19, 2019.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Noel A. Radcliffe, Hillsboro, Wisconsin; Richard A. Radcliffe, Sparta, Wisconsin; Robin W. Radcliffe, Brooktondale, New York; and Rolfe M. Radcliffe, Berkshire, New York, each individually and acting in concert;* to acquire voting shares of BRAD, Inc., and thereby indirectly acquire shares of Black River Country Bank, both of Black River Falls, Wisconsin.

B. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *City Bank and Kendra B. Lane, both of Lubbock, Texas, as Trustees of the South Plains Financial, Inc., Employee Stock Ownership Plan, Lubbock, Texas ('ESOP') and Robert C. Dean, and Kendra B. Lane, all of Lubbock, Texas, as members of the ESOP Investment Committee;* to acquire voting shares of the ESOP and thereby indirectly acquire South Plains Financial, Inc., and City Bank, both of Lubbock, Texas.

Board of Governors of the Federal Reserve System, February 27, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–03845 Filed 3–1–19; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Revised Jurisdictional Thresholds for Section 8 of the Clayton Act

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The Federal Trade Commission announces the revised thresholds for interlocking directorates required by the 1990 amendment of Section 8 of the Clayton Act. Section 8 prohibits, with certain exceptions, one person from serving as a director or officer of two competing corporations if two thresholds are met. Competitor corporations are covered by Section 8 if each one has capital, surplus, and undivided profits aggregating more than $10,000,000, with the exception that no corporation is covered if the competitive sales of either corporation are less than $1,000,000. Section 8(a)(5) requires the Federal Trade Commission to revise those thresholds annually, based on the change in gross national product. The new thresholds, which take effect immediately, are $36,564,000 for Section 8(a)(1), and $3,656,400 for Section 8(a)(2)(A).

DATES: March 4, 2019.

FOR FURTHER INFORMATION CONTACT: James F. Mongoven (202–326–2879), Bureau of Competition, Office of Policy and Coordination.

(Authority: 15 U.S.C. § 19(a)(5))

April J. Tabor,

Acting Secretary.

[FR Doc. 2019–03396 Filed 3–1–19; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

Revised Jurisdictional Thresholds for Section 7a of the Clayton Act

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The Federal Trade Commission announces the revised thresholds for the Hart-Scott-Rodino Antitrust Improvements Act of 1976 required by the 2000 amendment of Section 7A of the Clayton Act.

DATES: April 3, 2019.

FOR FURTHER INFORMATION CONTACT: Nora Whitehead (202–326–3100), Federal Trade Commission, Bureau of Competition, Premerger Notification Office, 400 7th Street SW, Room 5301, Washington, DC 20024.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, Public Law 94–435, 90 Stat. 1390 (''the Act''), requires all persons contemplating certain mergers or acquisitions, which meet or exceed the jurisdictional thresholds in the Act, to file notification with the Commission and the Assistant Attorney General and to wait a designated period of time before consummating such transactions. Section 7A(a)(2) requires the Federal Trade Commission to revise those thresholds annually, based on the change in gross national product, in accordance with Section 8(a)(5). Note that while the filing fee thresholds are revised annually, the actual filing fees are not similarly indexed and, as a result, have not been adjusted for inflation in over a decade. The new thresholds, which take effect 30 days after publication in the **Federal Register**, are as follows:

Subsection of 7A	Original threshold (million)	Adjusted threshold (million
7A(a)(2)(A)	$200	$359.9
7A(a)(2)(B)(i)	50	90
7A(a)(2)(B)(i)	200	359.9
7A(a)(2)(B)(ii)(i)	10	18
7A(a)(2)(B)(ii)(i)	100	180
7A(a)(2)(B)(ii)(II)	10	18
7A(a)(2)(B)(ii)(II)	100	180
7A(a)(2)(B)(ii)(III)	100	180
7A(a)(2)(B)(ii)(III)	10	18
Section 7A note: Assessment and Collection of Filing Fees [1] (3)(b)(1)	100	180
Section 7A note: Assessment and Collection of Filing Fees (3)(b)(2)	100	180
Section 7A note: Assessment and Collection of Filing Fees (3)(b)(2)	500	899.8
Section 7A note: Assessment and Collection of Filing Fees (3)(b)(3)	500	899.8

[1] Public Law 106–553, Sec. 630(b) amended Sec. 18a note.

Any reference to these thresholds and related thresholds and limitation values in the HSR rules (16 CFR parts 801–803) and the Antitrust Improvements Act Notification and Report Form (''the HSR Form'') and its Instructions will also be adjusted, where indicated by the term ''(as adjusted)'', as follows:

Original threshold	Adjusted threshold (million)
$10 million	$18
$50 million	90
$100 million	180
$110 million	198
$200 million	359.9
$500 million	899.8
$1 billion	1,799.5

By direction of the Commission.

April J. Tabor,

Acting Secretary.

[FR Doc. 2019–03395 Filed 3–1–19; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*Online Application Order Form for Products from the Healthcare Cost and Utilization Project (HCUP).*''

This proposed information collection was previously published in the **Federal Register** on December 18, 2018 and allowed 60 days for public comment. AHRQ received no substantive comments from members of the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by April 3, 2019.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Online Application Order Form for Products From the Healthcare Cost and Utilization Project (HCUP)

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. The Healthcare Cost and Utilization Project (HCUP, pronounced ''H-Cup'') is a vital resource helping the Agency achieve its research agenda, thereby furthering its goal of improving the delivery of health care in the United States. HCUP is a family of health care databases and related software tools and products developed through a Federal-State-Industry partnership and sponsored by AHRQ. HCUP includes the largest collection of longitudinal hospital care data in the United States, with all-payer, encounter-level information beginning in 1988. The HCUP databases are annual files that contain anonymous information from hospital discharge records for inpatient care and certain components of outpatient care, such as emergency care and ambulatory surgeries. The project currently releases seven types of databases created for research use on a broad range of health issues, including cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, State, and local market levels. HCUP also produces a large number of software tools to enhance the use of administrative health care data for research and public health use. Software tools use information available from a variety of sources to create new data elements, often through sophisticated algorithms, for use with the HCUP databases.

HCUP's objectives are to:

- Create and enhance a powerful source of national, state, and all-payer health care data.
- Produce a broad set of software tools and products to facilitate the use of HCUP and other administrative data.
- Enrich a collaborative partnership with statewide data organizations (that voluntarily participate in the project) aimed at increasing the quality and use of health care data.
- Conduct and translate research to inform decision making and improve health care delivery.

This project is being conducted by AHRQ through its primary contractor and subcontractor, IBM Watson Health and Social & Scientific Systems, Inc., pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the outcomes, cost, cost-effectiveness, and use of health care services and access to such services. 42 U.S.C. 299a(a)(3).

Method of Collection

The HCUP releases seven types of databases for public research use:

(1) The National Inpatient Sample (NIS) is the largest all-payer inpatient care database in the United States, yielding national estimates of hospital inpatient stays. The NIS approximates 20 percent of the discharges from all U.S. community hospitals and contains data from approximately 7 million hospital stays each year. NIS data releases are available for purchase from the HCUP Central Distributor for data years beginning in 1988.

(2) The Kids' Inpatient Database (KID) is the only all-payer inpatient care database for children in the United States. The KID was specifically designed to permit researchers to study a broad range of conditions and procedures related to child health issues. The KID contains a sample of 2 to 3 million discharges for children age 20 and younger from more than 4,200 U.S. community hospitals. KID data releases are available every third year starting in 1997.

(3) The Nationwide Emergency Department Sample (NEDS) is the largest all-payer ED database in the United States. It is constructed to capture information both on ED visits that do not result in an admission and on ED visits that result in an admission to the same hospital. The NEDS contains more than 31 million unweighted records for ED visits at about 950 U.S. community hospitals and approximates a 20-percent stratified sample of U.S. hospital-based EDs. NEDS data releases are available beginning with data year 2006.

(4) The State Inpatient Databases (SID) contain the universe of inpatient discharge abstracts from data organizations in 48 States and the District of Columbia that currently participate in the SID. Together, the SID encompass approximately 97 percent of all U.S. community hospital discharges. Most States that participate in the SID make their data available for purchase through the HCUP Central Distributor. Files are available beginning with data year 1990.

(5) The State Ambulatory Surgery and Services Databases (SASD) contain encounter-level data from ambulatory surgery and other outpatient services from hospital-owned facilities. In addition, some States provide data for ambulatory surgery and outpatient services from nonhospital-owned facilities. Currently, 35 States participate in the SASD. Files are available beginning with data year 1997.

(6) The State Emergency Department Databases (SEDD) contain data from hospital-owned emergency departments (ED) for visits that do not result in a hospitalization. Currently, 38 States participate in the SEDD. Files are available beginning with data year 1999.

(7) The Nationwide Readmissions Database (NRD) is designed to support various types of analyses of national readmission rates. This database addresses a large gap in health care data—the lack of nationally representative information on hospital readmissions. The NRD is a calendar-year, discharge-level database constructed from the HCUP State Inpatient Databases (SID).

To support AHRQ's mission to improve health care through scientific research, HCUP databases and software tools are disseminated to users outside of the Agency through a mechanism known as the HCUP Central Distributor at *https://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp.* The HCUP Central Distributor assists qualified researchers to access uniform research data across multiple states with the use of one application process. The HCUP databases disseminated through the Central Distributor are referred to as ''restricted access public release files''; that is, they are publicly available, but only under restricted conditions.

This information collection request is for the activities associated with the HCUP database application process, not the collection of health care data for HCUP databases.

The activities associated with this application include:

(1) HCUP Application. All persons requesting access to the HCUP databases must complete an application at *https://distributor.hcup-us.ahrq.gov/.* Applications for HCUP State databases require a brief description of the planned research use to ensure that the intended use is consistent with HCUP policies and with the HCUP Data Use Agreement (DUA). Paper versions of all application packages are also available for downloading at *http://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp.*

(2) HCUP DUA Training. All persons wanting access to the HCUP databases must complete an online training course. The purpose of the training is to emphasize the importance of data protection, reduce the risk of inadvertent violations, and describe the individual's responsibility when using HCUP data. The training course can be accessed and completed online at *http://www.hcup-us.ahrq.gov/techassist/dua.jsp.*

(3) HCUP DUA. All persons wanting access to the HCUP databases must sign a data use agreement. An example DUA for the Nationwide databases is available at *http://www.hcup-us.ahrq.gov/team/NationwideDUA.jsp.*

HCUP databases are released to researchers outside of AHRQ after the completion of required training and submission of an application that includes a signed HCUP DUA. In addition, before restricted access public release state-level databases are released, AHRQ must review and approve the applicant's statement of intended use to ensure that the planned use is consistent with HCUP policies and with the HCUP DUA. Fees are set for databases released through the HCUP Central Distributor depending on the type of database. The fee for sale of state-level data is determined by each participating Statewide Data Organization and reimbursed to those organizations. Information collected in the HCUP Application process will be used for two purposes only:

1. Business Transaction: In order to deliver the HCUP databases and software, contact information is necessary for shipping some types of HCUP data on disk (or any other media used in the future).

2. Enforcement of the HCUP DUA: The HCUP DUA contains several restrictions on use of the data. Most of these restrictions have been put in place to safeguard the privacy of individuals and establishments represented in the data. For example, data users can only use the data for research, analysis, and aggregate statistical reporting and are prohibited from attempting to identify any persons in the data. Contact information on HCUP DUAs is retained in the event that a violation of the DUA takes place.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden associated with the applicants' time to order any of the HCUP databases. An estimated 1,500 persons will order HCUP data annually. Each of these persons will complete an application (10 minutes), the DUA training (15 minutes) and a DUA (5 minutes). The total burden is estimated to be 750 hours annually.

Exhibit 2 shows the estimated annualized cost burden associated with the applicants' time to order HCUP data. The total cost burden is estimated to be $29,662 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
HCUP Application Form	1,500	1	10/60	250
HCUP DUA Training	1,500	1	15/60	375
HCUP DUA	1,500	1	5/60	125
Total	4,500	na	na	750

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
HCUP Application Form	1,500	250	$39.55	$9,887
HCUP DUA Training	1,500	375	39.55	14,831
HCUP DUA	1,500	125	39.55	4,944
Total	4,500	750	na	29,662

* *Based upon the mean of the average wages for Life Scientists, All Other (19–1099), National Compensation Survey:* Occupational Employment Statistics, May 2017 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2019–03734 Filed 3–1–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–1099]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Capacity Building Assistance Program: Assessment and Quality Control to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on September 6, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Capacity Building Assistance Program: Assessment and Quality Control—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) is requesting the Office of Management and Budget (OMB) to grant a one year revision to

collect data that comprises the Health Professional Application for Training, Training Follow-up Instrument, and the Technical Assistance Satisfaction Instrument. For this one year revision we will not collect any qualitative data (interviews) since we have gleaned valuable information that has been used to improve our service delivery and processes. The purpose of this information collection is to assess how well the CDC's CBA program meets the needs of its consumers in order to enhance its capacity building strategy over time. The PTCs and CBA providers are funded by CDC/Division of STD Prevention (DSTDP) and Division of HIV/AIDS Prevention (DHAP) over a five-year period to provide capacity building services that includes information, training, and technical assistance. CBA means the provision of free (not for fee) information, training, technical assistance, and technology transfer to individuals, organizations, and communities to improve their capacity in the delivery and effectiveness of evidence-based interventions and core public health strategies for HIV prevention. CBA is provided to support health departments, community-based organizations, and healthcare organizations in the implementation, monitoring and evaluation of evidence-based HIV prevention interventions and programs; building organizational infrastructure; and community mobilization to decrease stigma and increase HIV testing in high risk communities. CBA services are requested by health departments, community-based organizations, and healthcare organizations and also offered proactively. Under this project, there will be no duplication of information collection, because it builds on existing, OMB approved data collection activities. The PTCs and CBA providers offer classroom and experiential training, web-based training, clinical consultation, and capacity building assistance to maintain and enhance the capacity of healthcare professionals to control and prevent STDs and HIV. The CBA service recipients are healthcare professionals who work at community-based organizations (CBOs), health departments, and healthcare organizations, most of whom are funded directly or indirectly by the CDC, involved in HIV prevention service delivery. Their positions include HIV educator, clinical supervisor, HIV prevention specialist, clinician, outreach worker, case manager director, program coordinator, program manager, disease intervention specialist, partner services provider, physicians, nurses, and health educators.

CDC is requesting to use two web-based assessments that will be administered to recipients of CBA services: (1) Training Follow-Up Instrument and (2) Technical Assistance Satisfaction Instrument. The first quantitative assessment will be disseminated 90 days after a training event to agency staff who participated in a training activity. It takes approximately 15 minutes to complete. The purpose of this web-based assessment is to determine the training participants' satisfaction with the trainers, training materials, and the course pace, benefits from the training, and CBA needs, how relevant the training was to their work, and whether they were able to utilize the information gained from the training. The second quantitative assessment will be disseminated 45 days after a technical assistance event to agency staff who participated in a technical assistance. This instrument takes approximately 15 minutes to complete. The purpose of the second assessment is to assess participants' satisfaction with the technical assistance they received, intended or actual use of enhanced capacity, barriers and facilitators to use, and benefits of the technical assistance. The 7,400 respondents represent an average of the number of health professionals who receive training and technical assistance from the CBA and PTC grantees during the years 2010 and 2011. The data collection is necessary (a) to assess CBA consumers' (community-based organizations, health departments, and healthcare organizations) satisfaction with and short-term outcomes from the overall CBA program as well as specific elements of the CBA program; (b) to improve CBA services and enhance the Capacity Building Branch's national capacity building strategy over time; (c)to assess the performance of the grantees in delivering training and technical assistance and to standardize the registration processes across the two CBA programs (*i.e.,* the PTC program and the CBA program) and multiple grantees funded by each program. There are no costs to respondents. The estimated annualized burden hours for this data collection activity are 8,633 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)
Healthcare Professionals	Health Professional Application for Training (HPAT).	7,400	2	5/60
Healthcare Professionals	Training Follow-up Instrument	3,700	2	15/60
Healthcare Professionals	Training Telephone Script	3,700	2	15/60
Healthcare Professionals	Technical Assistance (TA) Satisfaction Instrument.	3,700	2	15/60
Healthcare Professionals	Technical Assistance Telephone Script	3,700	2	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–03770 Filed 3–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–0010; Docket No. CDC–2019–0005]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the Birth Defects Study To Evaluate Pregnancy exposureS (BD–STEPS). The purpose of BD–STEPS is to identify modifiable maternal exposures in pregnancy that may increase the risk for having a pregnancy affected by certain major, structural birth defects. This revision proposes to add stillbirths without defects to the study population for two Centers and implement a supplemental telephone interview for these two Centers' stillbirths (with and without birth defects) and their controls.

DATES: Written comments must be received on or before May 3, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0005 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Lead, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposures (BD–STEPS) (formerly titled The National Birth Defects Prevention Study (NBDPS)), (OMB Control No. 0920–0010, Expiration 02/29/2020)—Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects currently covering three counties in Metropolitan Atlanta. Since 1997, CDC has funded case-control studies of major birth defects that utilize existing birth defect surveillance registries (including MACDP) to identify cases and study birth defects causes in participating states/municipalities across the United States.

The current study, BD–STEPS, is a case-control study that is similar to the previous CDC-funded birth defects case-control study, NBDPS, which stopped interviewing participants in 2013. As with NBDPS, BD–STEPS control infants are randomly selected from birth certificates or birth hospital records; mothers of case and control infants are interviewed using a computer-assisted telephone interview.

The results from NBDPS have improved understanding of the causes of birth defects. Over 200 articles have been written in professional journals using the data from NBDPS, and BD–STEPS data will soon be added to NBDPS data for analysis. The current BD–STEPS revision is an addition to the study population for two BD–STEPS Centers. Specifically, in these two Centers mothers of stillbirths without major birth defects will be added to the study population for BD–STEPS and mothers of all stillbirths (with and without birth defects) and all controls in these two Centers will be asked to participate in a supplemental telephone interview.

The BD–STEPS interview takes approximately 55 minutes to complete and is 10 minutes longer than the previously OMB-approved interview (the burden estimate includes both the introductory telephone script/consent and questionnaire). For the five Centers not participating in the stillbirth component of the study, a maximum of 370 interviews are planned per year per center, 270 cases and 100 controls; for the two Centers participating in additional stillbirth interviews, 590 interviews are planned per Center, 270 cases with birth defects, 100 controls, and 220 stillbirths without birth defects. With seven Centers and a maximum of 3,040 interviews, the maximum interview burden for all centers combined would be 2,787 hours per

year over three years. The 55 minute burden includes the time for the telephone consent script which is reviewed with the mother at the beginning of the call to collect the information via the CATI interview.

Five of the seven BD–STEPS Centers request consent for retrieval of leftover newborn bloodspots. If a maximum of 2,600 interviews would be expected for seven Centers, a maximum of 1,850 would be expected for five Centers (excluding stillbirths, for which newborn bloodspots are not available). A maximum of 15 minutes would be expected for the participant to read the bloodspot retrieval consent request and to read and sign the consent form. The anticipated maximum burden for bloodspot consent would be 463 hours annually.

With a maximum of 2,600 interviews planned annually, and approximately one third of the respondents eligible for the online questionnaire (selected based on reporting occupations queried in the questionnaire), a maximum of 830 women would receive the online questionnaire. Completion of the online questionnaire is estimated to take 20 minutes including reading introductory communication. The anticipated maximum burden for the online questionnaire is 277 hours annually.

We will request the release of reportable infectious diseases information from all women who complete the CATI. Of the 2,600 interviews planned annually, a maximum of 2,600 women would receive the infectious disease information request. Based on experience with consent forms, we expect the review, signing and mailing of the release of reportable infectious diseases information to take a maximum of 15 minutes for participants. The anticipated maximum burden for the reportable infectious diseases information is 650 hours annually.

In the two Centers participating in the supplemental interview, mothers of infants with or without birth defects that are stillborn and controls will be asked to participate in a supplemental telephone interview. The 25 minute supplemental interview will include the time for informed consent (Attachment Z). Based on a maximum of 640 women to be interviewed with the supplemental questionnaire, the maximum burden time would be 267 hours annually.

The total estimates of annual burden hours for all activities for all individuals for all Centers is 4,443 hours. The estimates of annualized burden hours represent the total population however due to lower participation rates (no more than 60%, the actual burden will be lower as well. There are no costs to the respondents other than their time.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents *	Number of responses per respondent	Average burden per response (In hours)	Total burden hours
Mothers (interview)	Telephone Consent Script (Attachment S1/S2)/BD–STEPS Computer Assisted Telephone Interview (Attachment C1/C2).	3,040	1	55/60	2,787
Mothers (consent for bloodspot retrieval).	Written consent for bloodspot retrieval (Attachment T1/T2 and U1/U2).	1,850	1	15/60	463
Mothers (online occupational questionnaire).	Online Occupational Questionnaire (Attachment M1–8).	830	1	20/60	277
Mothers (infectious disease release review).	Infectious Disease Request Form (Attachment D1/D2).	2,600	1	15/60	650
Mothers of all AR/MA stillbirths and controls (supplemental telephone interview).	Telephone consent and supplemental interview (Attachment N1/N2).	640	1	25/60	267
Total					4,443

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–03772 Filed 3–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–19–0017]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *Application for Training* (OMB Control No. 0920–0017) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on December 10, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Application for Training (OMB No. 0920–0017, expiration 06/30/2019)—Revision—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CSELS requests a three year approval for a revision to the Training and Continuing Education Online (TCEO) system, which will comprise four data collection and management tools. Requested revisions are (1) to add questions to the existing TCEO New Participant Registration and (2) to introduce a Post-Course Evaluation and a Follow-Up Evaluation. No changes are requested for the existing TCEO Proposal Tool.

TCEO provides access to CDC educational activities that offer continuing education to public health and healthcare professionals (learners) to maintain their professional licensures and certifications. Licensures and certifications are mandatory for certain health professionals to provide services that prevent and mitigate illness and save lives. Employees of hospitals, universities, medical centers, state and local health departments, and federal agencies participate in CDC's accredited educational activities to learn about current public health and healthcare practices. CDC is accredited by seven accreditation organizations to provide continuing education for public health and healthcare professionals.

CDC and CDC-funded educational activities include classroom study, conferences, and electronic learning (e-learning). The TCEO Proposal expedites submission, review, and accreditation processes for these CDC and CDC-funded educational activities. The information collected from educational developers provides CDC with the information necessary to meet accreditation requirements. CDC reviews proposals to ensure compliance with requirements and awards continuing education when activities meet accreditation standards. The educational activities that can offer continuing education are then added to TCEO for learners to access.

Accreditation organizations require a method of tracking learners who complete an educational activity and some require collection of profession-specific data, among other requirements. CDC requires health professionals who seek continuing education to establish an account by completing the TCEO New Participant Registration. CDC relies on this electronic form to collect information needed to coordinate learner registrations for educational activities.

The proposed inclusion of two new evaluation tools is required by accreditation organizations to ensure compliance with accreditation standards. Public health professionals will be required to take the TCEO Post-course Evaluation after they have participated in an educational activity and before they can earn continuing education. Health professionals who have received continuing education for the activity will be encouraged to complete the TCEO Follow-up Evaluation when a link is sent to them from TCEO by email. Reports on responses to both tools will be submitted to accreditation organizations when they conduct audits or when CDC requests renewal of accreditation. Both new tools provide information to help CDC improve the quality of its educational activities.

Proposed changes will ensure that CDC is in compliance with accreditation requirements, and improve the quality of educational activities, while continuing to offer accredited educational activities at no cost to learners. Because of the increasing demand for accredited educational activities that offer free CE for licensures and certifications, TCEO experiences a continued increase in educational activities completed each year by registered learners. Every year, the number of times learners complete steps to earn continuing education increases by approximately 15%. The two new evaluation tools will be shared with all learners who complete educational activities in TCEO, causing the annual burden estimate to increase significantly. The annual burden table has been updated to reflect the new TCEO Post-course Evaluation (66,667 burden hours) and the new TCEO Follow-up Evaluation (2,000 burden hours), for a total of 85,934 burden hours. There are no costs to respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Educational Developers (Health Educators)	TCEO Proposal	120	1	5
Public Health and Health Care Professionals (Learners)	TCEO New Participant Registration	200,000	1	5/60
Public Health and Health Care Professionals (Learners)	TCEO Post-course Evaluation	200,000	2	10/60
Public Health and Health Care Professionals (Learners)	TCEO Follow-up Evaluation	20,000	2	3/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–03773 Filed 3–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–19–19BN]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *Emergency Cruise Ship Outbreak Investigations (CSOIs)* to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on November 27, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Emergency Cruise Ship Outbreak Investigations (CSOIs)—Existing Collection in Use without an OMB Control Number—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Established in 1975 as a cooperative activity with the cruise ship industry, the Centers for Disease Control and Prevention (CDC) Vessel Sanitation Program (VSP) develops and implements comprehensive sanitation programs to minimize the risk of gastrointestinal diseases, by coordinating and conducting operational inspections, ongoing surveillance of gastrointestinal illness, and outbreak investigations on vessels.

Under the authority of the Public Health Service Act (42 U.S.C. Sections 264 and 269), the VSP is requesting a three-year approval for a new generic clearance information collection request (ICR). This ICR will provide the quick turn-around necessary to conduct emergency cruise ship outbreak investigations (CSOIs) in response to acute gastroenteritis (AGE) outbreaks. CSOIs are used to determine the causative agents and their sources, modes of transmission, or risk factors. The VSP's jurisdiction includes passenger vessels carrying 13 or more people sailing from foreign ports and within 15 days of arriving at a U.S. port.

VSP uses its syndromic surveillance system called the Maritime Illness and Death Reporting System (MIDRS) (approved under ''Foreign Quarantine Regulations'' [OMB Control No. 0920–0134, expiration date 05/31/2019]) to collect aggregate data about the number of people onboard ships in VSP's jurisdiction who are experiencing AGE symptoms. When the levels of illness meet VSP's alert threshold (*i.e.,* at least 2% in either the passenger or crew populations), a special report is made to VSP via MIDRS and remote environmental health and epidemiologic assistance is provided. VSP considers an outbreak to be ≥3% of reportable AGE cases in either guest or crew populations. When assistance is needed due to AGE outbreaks on cruise ships, this often requires VSP to deploy a response team to meet the ship in port within 24 hours of reaching the outbreak threshold, and in some cases deploying the response team to board the ship before its U.S. arrival and sail back to the U.S. port of disembarkation to conduct a more detailed and comprehensive epidemiologic and environmental health evaluation of the outbreak.

Causative agent, sources of exposure, modes of transmission, and risk factors can be ascertained by gathering the following types of information from both the affected and (seemingly) unaffected populations:

- Demographic information,
- Pre-embarkation travel information,
- Symptoms, including type, onset, duration,
- Contact with people who were sick or their body fluids,
- Participation in ship and shore activities,
- Locations of eating and drinking, and
- Foods and beverages consumed both on the ship and on shore.

Rapid and flexible data collection is imperative given the mobile environment, the remaining duration of the voyage left for investigation, and the loss to follow-up if delays allow passengers to disembark and leave the ship, including those returning to locations outside of the U.S.

This new generic clearance will cover investigations that meet all of the following criteria:

- The investigation is urgent in nature (*i.e.,* timely data are needed to inform rapid public health action to prevent or reduce morbidity or mortality).
- The investigation is characterized by undetermined agents, undetermined sources, undetermined modes of transmission, or undetermined risk factors.
- One or more CDC staff (including trainees and fellows) will be deployed to the field.
- Most CSOIs involve two to five days of data collection; data collection is completed in 30 days or less.

This new generic clearance excludes each of the following:

- Investigations related to non-urgent outbreaks or events.
- Investigations conducted for the primary purpose of program evaluation, surveillance, needs assessment, or research (*e.g.,* to contribute to generalizable knowledge).
- Investigations with data collection expected for greater than 30 days.

The VSP estimates 10 CSOIs annually in response to cruise ship AGE

outbreaks. The estimated number of respondents is 2,500 per CSOI, for a total of 25,000 respondents per year. The average time burden is 15 minutes for each respondent. Therefore, the total estimated annual burden in hours is 6,250. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Cruise Ship Passengers or Crew	Questionnaire	24,750	1	15/60
	Interview	250	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–03774 Filed 3–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–1143; Docket No. CDC–2019–0009]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled US Zika Pregnancy registry, is to seek Paperwork Reduction Act (PRA) clearance to monitor the frequency and types of adverse birth outcomes for women with laboratory evidence of Zika virus infection during pregnancy and their infants and to strengthen the public health response to the Zika virus disease outbreak.

DATES: CDC must receive written comments on or before May 3, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0009 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Lead, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

US Zika Pregnancy Registry (OMB Control No. 0920–1143, Expiration 11/30/2019)—Extension—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western Hemisphere, with autochthonous cases identified in Brazil. As of March 16, 2016, local transmission has been identified in at least 32 countries or territories in the Americas. Further spread to other countries in the region is likely. Local vector-borne transmission of Zika virus has not been documented in the 50 U.S. states or the District of Columbia, but has occurred in US territories, including in Puerto Rico, the US Virgin Islands, and American Samoa. However, Zika virus infections have been reported in travelers returning to the United States from areas with active Zika virus transmission. Zika virus infection also has occurred through sexual transmission, which may pose an additional risk to non-travelling pregnant women whose partners may have traveled to areas at high risk for Zika virus acquisition. With the ongoing outbreak in the Americas, the number of Zika virus disease cases among travelers returning to the United States likely will

increase, and sexual transmission from male travelers to their sex partners in the United States will likely continue to occur. In addition, mosquito-borne local transmission may occur in states where Aedes species mosquitoes are present.

In some Brazilian states where Zika virus transmission has occurred, there has been an increase in cases of infants born with microcephaly. Zika virus infections have been confirmed in several infants with microcephaly and in fetal losses in women infected during pregnancy. In addition to microcephaly, a range of other problems have been detected among fetuses and infants infected with Zika virus before birth, such as absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth. The Ministry of Health in Brazil, with support from the Pan American Health Organization (PAHO), the U.S. Centers for Disease Control and Prevention (CDC), and other partners, is investigating the association between Zika virus infection and microcephaly, as well as other adverse pregnancy and infant outcomes.

Zika virus disease and Zika virus congenital infection are nationally notifiable conditions for which the Council of State and Territorial Epidemiologists (CSTE) has established interim case definitions. All 50 states, the District of Columbia, and Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Northern Mariana Islands currently participate in reporting of arboviral diseases through ArboNET. However, ArboNET does not capture all the information needed to provide timely situational awareness in the context of the ongoing public health response. In particular, ArboNET collects limited data on pregnancy, pregnancy and birth outcomes, and congenital infections, all of which are necessary for informing ongoing response efforts.

As part of the public health response to the Zika virus disease outbreak, CDC will conduct supplemental surveillance of antenatal diagnostic testing and clinical outcomes among pregnant women with laboratory evidence of Zika virus or unspecified flavivirus infection and their infants through the U.S. Zika Pregnancy Registry. It is anticipated that the Registry will provide critical information to direct CDC clinical recommendations and public health guidance and messages.

The data to be collected for the Registry includes information about Zika infection-related tests and procedures conducted as part of the mother's and child's routine clinical care, and in line with existing CDC, American College of Obstetricians and Gynecologists and Society of Maternal Fetal Medicine, and American Academy of Pediatrics recommendations for evaluation, diagnosis, and follow-up of women infected with Zika virus during pregnancy and their children. No additional tests or procedures will be performed specifically for Registry purposes.

This request is submitted to extend the collection period of collection OMB number 0920–1143 for an additional three years. The total estimated annual burden hours are 23,833. There are no costs to the respondents other than their time.

ESTIMATES OF ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
State, Territorial and Local Health Departments.	Maternal Health History Form	1,100	10	30/60	5,500
	Supplemental Imaging Form	1,100	10	10/60	1,833
	Laboratory Results Form	1,100	10	15/60	2,750
Clinicians and Other Providers	Assessment at Delivery Form	1,100	10	30/60	5,500
	Infant Health Follow-Up Form	1,100	30	15/60	8,250
Total					23,833

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–03775 Filed 3–1–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

[OMB #0985–0059]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data Collection Materials for the Annual Performance Reporting of the Administration for Community Living's American Indian, Alaskan Natives and Native Hawaiian Programs

AGENCY: Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to the Revision of a Currently Approved Collection (ICR Rev) and solicits comments on the information collection requirements related to the annual Program Performance Report (PPR) for the American Indian, Alaskan Natives and Native Hawaiian Programs under Title VI of the Older Americans Act.

DATES: Submit written comments on the collection of information by April 3, 2019.

ADDRESSES: Submit written comments on the collection of information by:

(a) *Email to: OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Kristen Hudgins, Social Science Analyst, Administration for Community Living, Washington, DC 20201, 202–795–7732 or *kristen.hudgins@acl.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The data collection materials for the annual performance data for the Administration for Community Living's American Indian, Alaskan Natives and Native Hawaiian Programs (OAA Title VI) is a revision of a currently approved annual program performance data collection (OMB# 0985–0059). These data collection materials have been updated to better align with comparable data collected for ACL's other nutritional, supportive, and caregiving grants. Proposed changes include adding data components and updating others for more accurate reporting of persons served and activities provided through the Title VI-funded programs. The revised data collection will provide data necessary to determine the effectiveness of the program. Some examples of these changes are updating definitions in Title VI to be more in line with Title III, asking for unduplicated numbers of people served for different services and the number of hours spent providing said services. Additionally, the caregiver portion of the PPR has been updated to collect more information around types of caregivers served and unduplicated numbers of caregivers. Another element added has to do with information on expenditures. This data collection will also support ACL in tracking performance outcomes and efficiency measures with respect to the annual and long-term performance targets established in compliance with the Government Performance Results Modernization Act (GPRAMA).

Comments in Response to the 60-Day Federal Register Notice

A notice was published in the **Federal Register** on August 15, 2018, Vol. 83, No. 158, pp. 40519–40520. ACL received comments from ten (10) organizations and two (2) individuals about the Program Performance Report (PPR) redesign. ACL reviewed all of the comments. However, some of the comments were deemed to not be relevant because they were: (a) About the data submission process itself; (b) did not request a change; (c) only related to format; or (d) indicated topics for technical assistance and training for the final data collection. For ease of review, the remaining comments and their responses have been grouped by topic or issue. The ACL responses for each topic/issue are detailed below:

Topic/issue	Comment	ACL response
Additional comment boxes for story telling.	One of the comments was to include a comment box to the PPR to allow for programs to better share their stories.	ACL has added a comment box at the end of the PPR for program staff to share contextual information about how their program is addressing the needs of Elders in their community.
Additional data reporting	There were some concerns expressed around having to keep track of and report additional data.	Although ACL understands that reporting can be a burdensome process, having better and richer data is a priority for the Title VI program, particularly where it allows us to align with the data collection for Title III.
"Tribal Organization"	There was a suggestion posited by two organizations to change the term "Tribal Organization" to something more encompassing.	ACL has decided to use the term "Grantee Name" to be more inclusive of tribal consortia, Native Hawaiian organizations, and other entities that did not feel covered under the previous term of "Tribal Organization".
Staffing/Volunteers	Five organizations commented that they found the prospect of collecting data on volunteers and their hours to be an unnecessary reporting burden.	Upon consideration of the issues brought up through the FRN comments, ACL has decided to remove the question on volunteers and volunteer hours.
Nutrition Questions	There was one comment noting that there were too many questions around nutrition education and counseling.	ACL understands that reporting can be a burdensome process and so have updated the questions under "Other Nutrition Services" to only ask one additional question regarding number of persons receiving nutrition counseling. In keeping with Title III's SPR we have updated Nutrition Education hours to "sessions".
Meal Mileage	There were many comments (both positive and asking for clarification) related to a proposed question around home-delivered meal mileage.	ACL has decided to remove this question from the PPR and will consider posing it to grantees through a different data collection source at a later date.
Ombudsman	Removal of the ombudsman question	ACL will not add an ombudsman question back into the Title VI PPR as official ombudsman services should be reported through the State Ombudsman and collected in the NORS tool. However, ACL has decided to add in a question related to visiting nursing homes and other assisted living facilities as we agree that these activities are important to capture.
Other Supportive Services ...	Suggestions to add space for grantees to report on the types of supportive services they provide.	ACL has decided to add an optional text box for programs to share other supportive services they may offer that are not currently listed.
Transportation	Suggestions to split transportation into assisted and unassisted as they are in Title III's SPR.	ACL appreciates the suggestion to collect more data but has decided in the interest of balancing data collection and burden to not make the distinction between the different "types" of transportation provided by a program.

Topic/issue	Comment	ACL response
Social Events	Question about the purpose of ''social events held'' and whether it would be better to change to ''social/recreation events held'' to allow cost sharing with Title III.	Title III does not ask for this information. A social event, as it is being defined in Title VI, can be recorded as ''Other'' in SPR.
Finance Section for Part A/B	The comments on the newly added finance section for Part A/B were varied and ran from asking that the question be removed and others asking for more options to share data.	ACL is sensitive to the burden that may be caused by asking for new kinds of information from our grantees, we find that requiring this information will allow us to better advocate for our programs and their financial needs. Based on the comments ACL has added an optional text box for grantees to explain more about their financial situations, and has also added additional options under the section asking for types of funding used.
Caregiver (language)	Suggestions to change some of the language in the caregiver section to make it clearer.	ACL has updated the language in this section to be less wordy and using the term ''caregiver'' rather than ''persons'' to make it clearer that the intended recipients of services are caregivers and not those they care for.
Caregiver (Information and Assistance).	There were a couple of suggestions that Information and Assistance should be separated from one another.	ACL has chosen to maintain consistency in this area with Title III's SPR and will ensure that training and technical materials make it clear how we are defining Information and Assistance and how to best collect it.
Finance Section for Part C	Suggestion to not add the finance section and asking for the cost of respite care to be pulled out.	ACL is sensitive to the burden that may be caused by asking for new kinds of information from our grantees, we find that requiring this information will allow us to better advocate for our programs and their financial needs. ACL chose respite care from the five required services based on the thinking that the cost of this service would be easier to track.

The proposed form(s) may be found on the ACL website at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

Title VI funding is broken into three categories. Parts A and B are for nutritional and supportive programming, and ask for the same information. Part A is for American Indian and Alaska Native grantees, and Part B is for Native Hawaiian grantees. Part C is for caregiver programming. All Part C grantees must have Part A/B funding; but not all Part A/B grantees will have Part C programs. Therefore, there are 270 unique respondents, but only 237 will have to complete all portions of the PPR. ACL believes that the increase in burden hours is justified by the improved quality of the data and will ultimately improve the services provided to Native Elders.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
PPR Part A/B	270	1	1.83	494.1
PPR Part C	237	1	1.66	393.4
Total				887.5

Dated: February 22, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–03847 Filed 3–1–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3490]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exempt Infant Formula Production: Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 3, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0811. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records

OMB Control Number 0910–0811—Extension

Section 412(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350a(h)(1)) exempts an infant formula that is represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of section 412(a)–(c) of the FD&C Act. These formulas are customarily referred to as ''exempt infant formulas.'' Under part 106 (21 CFR part 106), we established requirements for quality factors for infant formulas and CGMPs, including quality control procedures. This collection of information will help prevent the manufacture of adulterated infant formula, ensure the safety of infant formula, and ensure that the nutrients in infant formula are present in a form that is bioavailable.

In the **Federal Register** of April 15, 2016 (81 FR 22174), we published a notice of availability for the guidance document entitled ''Guidance for Industry: Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.'' The guidance describes our current thinking on the manufacturing of exempt infant formula in relation to the requirements in part 106 for CGMPs, quality control procedures, conduct of audits, and records and reports that apply to nonexempt infant formulas. Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances.*

Our estimate of the burden of the recordkeeping recommendations includes the one-time burden of developing production and in-process control systems and the annual burdens of developing and maintaining aggregate production and control records, records pertaining to the distribution of infant formula, and records pertaining to regularly scheduled audits. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

The guidance recommended, to the extent practicable, that respondents include records required by part 106, subparts A, B, C, D, and F for non-exempt infant formulas. Because the records and reporting requirements related to part 106, subparts E and G are not generally applicable to exempt infant formula manufacturers, FDA is not recommending in the guidance that exempt infant formula manufacturers follow these requirements. As such, the records and reporting requirements in part 106, subparts E and G are not part of this information collection.

Description of Respondents: The respondent recordkeepers are manufacturers of exempt infant formula.

In the **Federal Register** of October 1, 2018 (83 FR 49393), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
First-Year Annual Burden:					
Production and In-Process Control System—106.6(c)(5) and 106.100(e)(1), and (e)(3).	3	1	3	40	120
Controls to Prevent Adulteration due to Automatic (Mechanical or Electronic) Equipment—106.35(c) and 106.100(f)(5).	3	1	3	6,400	19,200
Total First Year Only Hourly Recordkeeping Burden.					19,320
Recurring Annual Burden:					
Controls to Prevent Adulteration Caused by Facilities—Testing for Radiological Contaminants—106.20(f)(3).	4	1	4	1.5	6
Controls to Prevent Adulteration Caused by Facilities—Recordkeeping of Testing for Radiological Contaminants—106.20(f)(4) and 106.100(f)(1).	4	1	4	0.08 (5 minutes)	0.32
Controls to Prevent Adulteration Caused by Facilities—Testing for Bacteriological Contaminants—106.20(f)(3).	3	52	156	0.08 (5 minutes)	12.48
Controls to Prevent Adulteration Caused by Facilities—Recordkeeping of Testing for Bacteriological Contaminants—106.20(f)(4) and 106.100(f)(1).	3	52	156	0.08 (5 minutes)	12.48
Controls to Prevent Adulteration by Equipment or Utensils—106.30(d)(1) and 106.100(f)(2).	3	52	156	0.21 (13 minutes)	32.76
Controls to Prevent Adulteration by Equipment or Utensils—106.30(e)(3)(iii) and 106.100(f)(3).	3	52	156	0.21 (13 minutes)	32.76
Controls to Prevent Adulteration by Equipment or Utensils—106.30(f)(2) and 106.100(f)(4).	3	52	156	0.19 (11 minutes)	29.64

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Controls to Prevent Adulteration Due to Automatic (Mechanical or Electronic) Equipment—106.35(c) and 106.100(f)(5).	3	52	156	520	81,120
Controls to Prevent Adulteration Due to Automatic (Mechanical or Electronic) Equipment—106.35(c) and 106.100(f)(5).	3	2	6	640	3,840
Controls to Prevent Adulteration Caused by Ingredients, Containers, and Closures—106.40(g) and 106.100(f)(6).	3	52	156	0.17 (10 minutes)	26.52
Controls to Prevent Adulteration During Manufacturing—106.50 and 106.100(e).	3	52	156	0.23 (14 minutes)	35.88
Controls to Prevent Adulteration From Microorganisms—106.55(d), 106.100(e)(5)(ii), and 106.100(f)(7).	3	52	156	0.25 (15 minutes)	39
Controls to Prevent Adulteration During Packaging and Labeling of Infant Formula—106.60(c).	1	12	12	0.25 (15 minutes)	3
General Quality Control Testing—106.91(b)(1)–(3).	2	1	2	2	4
General Quality Control—106.91(b)(1), 106.91(d), and 106.100(e)(5)(i).	2	52	104	0.15 (9 minutes)	15.6
General Quality Control—106.91(b)(2), 106.91(d), and 106.100(e)(5)(i).	2	52	104	0.15 (9 minutes)	15.6
General Quality Control—106.91(b)(3), 106.91(d), and 106.100(e)(5)(i).	2	52	104	0.15 (9 minutes)	15.6
Audit Plans and Procedures—106.94; Ongoing Review and Updating of Audits.	3	1	3	8	24
Audit Plans and Procedures—106.94; Regular Audits.	3	52	156	4	624
Total Recurring Recordkeeping Burden					85,889.64
Total Recordkeeping Burden					105,209.64

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection, we made a correction since the last OMB approval. While the one-time estimated recordkeeping burden remains as 19,320 hours, we increased the annual estimated recurring recordkeeping burden to 85,889.64 hours due to a calculation error (a 79,561.58 hour increase) for a total recordkeeping burden of 105,209.64 hours.

Dated: February 27, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03824 Filed 3–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3240]

List of Bulk Drug Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is evaluating substances that have been nominated for inclusion on a list of bulk drug substances (active pharmaceutical ingredients) for which there is a clinical need (the 503B Bulks List). Drug products that outsourcing facilities compound using bulk drug substances on the 503B Bulks List can qualify for certain exemptions from the Federal Food, Drug, and Cosmetic Act (FD&C Act) provided certain conditions are met. This notice identifies two bulk drug substances that FDA has considered and is not including on the list at this time: Nicardipine hydrochloride and vasopressin. Additional bulk drug substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of future notices.

DATES: The announcement of the notice is published in the **Federal Register** on March 4, 2019.

ADDRESSES: Submit electronic comments on bulk drug substances nominated for the 503B Bulks List to Docket No. FDA–2015–N–3469. Submit written comments on bulk drug substances nominated for the 503B Bulks List to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Hankla, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5216,

Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

A. Drug Compounding

Compounded drug products can serve an important role for patients for whom an FDA-approved drug product is not appropriate, such as patients who have an allergy and need a medication to be made without a certain dye or hospital inpatients who need infusions of a drug combined with a particular diluent not specified in the approved product labeling. However, they also pose a higher risk to patients than FDA-approved drugs. In 2012, contaminated injectable drug products that a State-licensed compounding pharmacy shipped to patients and healthcare practitioners across the country caused a fungal meningitis outbreak that resulted in more than 60 deaths and 750 cases of infection.[1] This was the most serious of a long history of outbreaks and other serious adverse events associated with contaminated, superpotent, or otherwise poor quality compounded drugs.

In response to this outbreak, Congress enacted the Drug Quality and Security Act (Pub. L. 113–54), which, among other things, added new section 503B to the FD&C Act (21 U.S.C. 353b) and created a new category of compounders known as outsourcing facilities.[2] Drug products compounded by outsourcing facilities in accordance with the conditions of section 503B are exempt from the following three sections of the FD&C Act: Section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)); section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements).[3]

Drug products compounded under the conditions in section 503B are not exempt from current good manufacturing practice (CGMP) requirements in section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)).[4] Outsourcing facilities are also subject to FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that help to mitigate the risks of the drug products they compound.[5] Outsourcing facilities may or may not obtain prescriptions for identified individual patients and may, therefore, distribute compounded drugs to healthcare practitioners for ''office stock'' to hold in their offices in advance of patient need.[6]

Because compounded drug products are not FDA-approved, they have not undergone FDA premarket review for safety, effectiveness, and quality. Although outsourcing facilities must comply with CGMP requirements and are inspected by FDA according to a risk-based schedule, their drug products have not been determined to be safe or effective for the conditions of use reflected in drug product labeling and have not been subjected to a premarket inspection or associated with a finding of manufacturing quality, all of which are part of the drug approval process. Because compounded drug products are subject to a lower regulatory standard than FDA-approved drug products, they should only be used by patients who could not use an FDA-approved drug product.

When a compounded drug is appropriate for a patient, outsourcing facilities may be able to prepare that drug using an FDA-approved drug product as the starting material. On other occasions it may be necessary to compound the drug from a bulk drug substance.[7] Section 503B limits the bulk drug substances that outsourcing facilities can use in compounding to those that are used to compound drugs in shortage or that appear on a list developed by FDA of bulk drug substances for which there is a clinical need. Section 503B includes this limitation, among others, to help prevent outsourcing facilities from growing into conventional manufacturing operations making unapproved new drug products. Allowing outsourcing facilities to compound a drug product from a bulk drug substance that is a component of an FDA-approved drug product because of, for instance, economic incentives, when a patient's clinical needs could be met by the approved drug product or a drug product compounded from the approved drug product would reduce the incentive for applicants to seek FDA approval of drug products and to continue to market them. The drug approval process is critical to ensure pharmaceuticals meet regulatory standards established for quality, safety, and effectiveness. In addition, when it is feasible to compound a drug product by starting with an approved drug product, there are certain benefits of doing so over starting with a bulk drug substance, including benefits relating to the assurances associated with premarket review by FDA for safety, effectiveness, and quality.

In sum, section 503B's limitation on the 503B Bulks List to bulk drug substances for which there is a clinical need serves important public health functions. First, it helps to limit patient exposure to compounded drug products, which have not been demonstrated to be safe and effective, to those situations in which the compounded drug product is necessary for patient treatment. Second, it preserves the incentives for applicants to invest in the research and testing required to obtain FDA approval and to continue to manufacture FDA-approved drug products, thereby helping to maintain a supply of high-quality, safe, and effective drugs.

B. Statutory and Regulatory Background

Section 503B of the FD&C Act describes the conditions that must be satisfied for drug products compounded by an outsourcing facility to be exempt from the approval, labeling, and drug supply chain security requirements cited above.[8] One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for exemptions under section 503B is that the outsourcing facility may not compound a drug using a bulk drug substance unless the bulk drug substance appears on a list established by the Secretary of Health and Human

[1] See *https://www.cdc.gov/HAI/outbreaks/meningitis.html.*

[2] See Public Law 113–54, section 102(a), 127 Stat. 587, 587–588 (2013). Other compounders, which are not the subject of this notice, are regulated under section 503A of the FD&C Act (21 U.S.C. 353a). These include licensed pharmacists in State-licensed pharmacies or Federal facilities, and licensed physicians, who have not registered an outsourcing facility with FDA. Drug products compounded by section 503A compounders are exempt from sections 505 (new drug approval requirements), 502(f)(1) (labeling with adequate directions for use), and 501(a)(2)(B) (CGMP requirements) if the conditions of section 503A are met, including that compounding is based on the receipt of valid prescriptions for identified individual patients (section 503A(a)). In general, section 503A compounders do not register with and are not routinely inspected by FDA and are primarily overseen by the States.

[3] Section 503B(a) of the FD&C Act.

[4] Compare section 503A(a) of the FD&C Act (exempting drugs compounded in accordance with section 503A from CGMP requirements) with section 503B(a) of the FD&C Act (not exempting drugs compounded in accordance with section 503B from CGMP requirements).

[5] Section 503B(b)(4) and (5) of the FD&C Act.

[6] Section 503B(d)(4)(C) of the FD&C Act.

[7] For a fuller discussion of these issues, see FDA's guidance for industry entitled ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' (503B Bulks Evaluation Guidance), particularly sections II.B. and C., available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM602276.pdf.*

[8] Section 503B(a) of the FD&C Act.

Services identifying bulk drug substances for which there is a clinical need (the 503B Bulks List); or the drug compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act (FDA's drug shortage list) (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing.[9]

Section 503B directs FDA to establish the 503B Bulks List by (1) publishing a notice in the **Federal Register** proposing bulk drug substances to be included on the list, including the rationale for such proposal; (2) providing a period of not less than 60 calendar days for comment on the notice; and (3) publishing a notice in the **Federal Register** designating bulk drug substances for inclusion on the list.[10]

For purposes of section 503B, *bulk drug substance* means an active pharmaceutical ingredient as defined in 21 CFR 207.1(b).[11] *Active pharmaceutical ingredient* means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, but the term does not include intermediates used in the synthesis of the substance.[12] [13]

II. Methodology for Developing the 503B Bulks List

A. Process for Developing the List

In the **Federal Register** of December 4, 2013 (78 FR 72838), FDA requested nominations for specific bulk drug substances for the Agency to consider for inclusion on the 503B Bulks List. In response to that request, interested groups and individuals nominated a wide variety of substances. However, many of those nominations were not for substances used in compounding as active pharmaceutical ingredients or did not include sufficient information to allow FDA to evaluate the nominated substance. To improve the efficiency of the process for the development of the list of bulk drug substances, FDA reopened the nomination process in the **Federal Register** of July 2, 2014 (79 FR 37750) and provided more detailed information on what it needs to evaluate nominations for the list. On October 27, 2015 (80 FR 65770), the Agency opened a new docket, FDA–2015–N–3469, to provide an opportunity for interested persons to submit new nominations of bulk drug substances or to renominate substances with sufficient information.

As FDA evaluates bulk drug substances, it intends to publish notices for public comment in the **Federal Register** that describe its proposed position on each substance along with the rationale for that position.[14] After considering any comments on FDA's proposals regarding whether to include nominated substances on the 503B Bulks List, FDA intends to consider whether input from the Pharmacy Compounding Advisory Committee (PCAC) on the nominations would be helpful to the Agency in making its determination, and if so, it will seek PCAC input.[15] Depending on its review of the docket comments and other relevant information before the Agency, FDA may finalize its proposed determination without change, or it may finalize a modification to its proposal to reflect new evidence or analysis regarding clinical need. FDA will then publish in the **Federal Register** a final determination identifying the bulk drug substances for which it has determined there is a clinical need and FDA's rationale in making that final determination. FDA will also publish in the **Federal Register** a final determination regarding those substances it considered but found that there is no clinical need to use in compounding and FDA's rationale in making this decision.

FDA intends to maintain a current list of all bulk drug substances it has evaluated on its website, with separate lists for bulk drug substances it has placed on the 503B Bulks List and those it has decided not to place on the 503B Bulks List. FDA will only place a bulk drug substance on the 503B Bulks List where it has determined there is a clinical need for outsourcing facilities to compound drug products using the bulk drug substance. If a clinical need to compound drug products using the bulk drug substance has not been demonstrated, based on the information submitted by the nominator and any other information considered by the Agency, FDA will not place a bulk drug substance on the 503B Bulks List.

FDA intends to evaluate the bulk drug substances nominated for the 503B Bulks List on a rolling basis. FDA will evaluate and publish in the **Federal Register** its proposed and final determinations in groups of bulk drug substances until all nominated substances that were sufficiently supported have been evaluated and either placed on the 503B Bulks List or identified as bulk drug substances that were considered but determined not to be appropriate for inclusion on the 503B Bulks List.[16]

B. Analysis of Substances Nominated for the List

As noted above, section 503B(a)(2)(A)(i) provides that the 503B Bulks List is to include ''bulk drug substances for which there is a clinical need.'' The Agency is evaluating bulk drug substances that were nominated for inclusion on the 503B Bulks List, proceeding case by case, under the standard provided by the statute.[17] In applying this standard to make determinations regarding the substances set forth in this notice, FDA interprets the phrase ''bulk drug substances for which there is a clinical need'' to mean that the 503B Bulks List may include a bulk drug substance if: (1) There is a clinical need for an outsourcing facility to compound a drug product, and (2) the drug product must be compounded using the bulk drug substance. FDA is not interpreting supply issues, such as backorders, to be within the meaning of ''clinical need'' for compounding with a bulk drug substance. Section 503B separately provides for compounding from bulk drug substances under the exemptions from the FD&C Act discussed above if the drug product compounded from the bulk drug

[9] Section 503B(a)(2)(A) of the FD&C Act.

[10] Section 503B(a)(2)(A)(i)(I) to (III) of the FD&C Act.

[11] 21 CFR 207.3.

[12] Section 503B(a)(2) of the FD&C Act and 21 CFR 207.1.

[13] Inactive ingredients are not subject to section 503B(a)(2) of the FD&C Act and will not be included in the 503B Bulks List because they are not included within the definition of a bulk drug substance. Pursuant to section 503B(a)(3), inactive ingredients used in compounding must comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists.

[14] This is consistent with procedures set forth in section 503B(a)(2)(A)(i). Although the statute only directs FDA to issue a **Federal Register** notice and seek public comment when it proposes to include bulk drug substances on the 503B Bulks List, we intend to seek comment when the Agency has evaluated a nominated substance and proposes either to include or not to include the substance on the list.

[15] Section 503B does not require FDA to consult the PCAC before developing a 503B Bulks List.

[16] On June 10, 2016 (81 FR 37502), FDA announced the availability of a guidance for industry (revised January 2017) entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act''; available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.* This guidance provides additional information regarding FDA's policies for bulk drug substances nominated for the 503B Bulks List pending our review of nominated substances under the ''clinical need'' standard.

[17] See 503B Bulks Evaluation Guidance, supra n.7 (describing FDA's policies for developing the 503B Bulks List, including the interpretation of the phrase ''bulk drug substances for which there is a clinical need,'' as it is used in section 503B).

substance is on the FDA drug shortage list at the time of compounding, distribution, and dispensing. Additionally, we are not considering cost of the compounded drug product as compared with an FDA-approved drug product when assessing ''clinical need.''

The bulk drug substances that we are addressing in this notice are components of FDA-approved drug products, and we evaluated them by asking the following questions:

(1) Is there a basis to conclude, for each FDA-approved product that includes the nominated bulk drug substance, that (a) an attribute of the FDA-approved drug product makes it medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation, and (b) the drug product proposed to be compounded is intended to address that attribute?

(2) Is there a basis to conclude that the drug product proposed to be compounded must be produced from a bulk drug substance rather than from an FDA-approved drug product?

The reason for question (1) is that unless an attribute of the FDA-approved drug is medically unsuitable for certain patients, and the drug product to be compounded is intended to address that attribute, we do not expect that there will be a clinical need for a patient to use a compounded drug product. Rather, such compounding would unnecessarily expose patients to the risks associated with drug products that have not been shown to meet the standards applicable to FDA-approved drug products for safety, effectiveness, quality, and labeling and would undermine the drug approval process. The reason for question (2) is that to place a bulk drug substance on the 503B Bulks List, FDA must determine that there is a clinical need for outsourcing facilities to compound a drug product *using the bulk drug substance* rather than starting with an FDA-approved drug product.

If the answer to both of these questions is ''yes,'' there may be clinical need for outsourcing facilities to compound using the bulk drug substance, and we would analyze the question further.[18] If the answer to either of these questions is ''no,'' there generally would not be a basis to conclude that there is a clinical need to compound drug products using the bulk drug substance instead of administering or starting with an approved drug product, and we would generally not include the bulk drug substance on the 503B Bulks List.

III. Substances Proposed for the 503B Bulks List

In August 2018, the Agency issued a **Federal Register** notice in which it evaluated three nominated bulk drug substances under the statutory standard—bumetanide, nicardipine hydrochloride, and vasopressin—and proposed not to include them on the 503B Bulks List (the August notice). In this notice, after review of the comments submitted to the docket for the August notice, FDA is making its final determination with regard to nicardipine hydrochloride and vasopressin. At this time, FDA is not making a final determination regarding bumetanide. This substance remains under consideration by FDA.

1. Nicardipine Hydrochloride

Nicardipine hydrochloride has been nominated for inclusion on the 503B Bulks List.[19] The proposed route of administration is intravenous, the proposed dosage form is injection, and the proposed strength is 0.1 to 2.5 milligrams per milliliter (mg/mL). This nominated bulk drug substance is a component of FDA-approved drug products (*e.g.,* NDAs 022276 and 019734). FDA has approved nicardipine hydrochloride drug products as 0.1 mg/mL and 0.2 mg/mL solutions ready for intravenous administration (or ''ready to use'') and as a 2.5 mg/mL single-dose vial that must be diluted prior to infusion.[20] [21] The single dose vial (NDA 022276) contains an excipient, benzoic acid; the ready-to-use solutions (NDA 019734) do not contain benzoic acid.

Because nicardipine hydrochloride is a component of FDA-approved drug products, we considered whether (1) there is a basis to conclude that an attribute of each FDA-approved drug product makes each one medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation, and the nicardipine hydrochloride drug product proposed to be compounded is intended to address that attribute in each FDA-approved drug product; and (2) whether the drug product proposed to be compounded must be compounded using a bulk drug substance.

a. Suitability of FDA-Approved Drug Products.

The nomination proposed to include on the list nicardipine hydrochloride injection compounded to concentrations of 0.1 mg/mL through 2.5 mg/mL. The nomination does not identify attributes of the approved nicardipine hydrochloride products that make them medically unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. Specifically, the nomination did not explain why ready-to-use nicardipine hydrochloride injection at 0.1 mg/mL and 0.2 mg/mL, and the 2.5 mg/mL single dose vial (for dilution) are medically unsuitable for certain patients.

A commenter on FDA's proposal not to include nicardipine hydrochloride on the 503B Bulks List indicated that an attribute of approved nicardipine hydrochloride injections, the presence of the excipient benzoic acid, makes those approved drug products medically unsuitable for patients who have an allergy to benzoic acid and that drug products would be compounded from the bulk drug substance nicardipine hydrochloride without benzoic acid. However, the commenter did not acknowledge the availability of FDA-approved benzoic acid-free nicardipine hydrochloride ready-to-use solutions for intravenous administration or explain why these approved drug products would be medically unsuitable for patients who have an allergy to benzoic acid.[22]

Accordingly, with respect to the nicardipine hydrochloride drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of each of the approved drug products makes each one medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation.

b. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

The nomination provided no basis to conclude that drug products containing nicardipine hydrochloride must be compounded using a bulk drug substance rather than using an FDA-approved drug product. The nomination

[18] Under the analysis described in FDA's 503B Bulks Evaluation Guidance, the additional analysis would consist of the consideration of four additional factors. We did not answer ''yes'' to both of the threshold questions for nicardipine hydrochloride or vasopressin, so we did not consider these additional factors in our determination not to include nicardipine hydrochloride or vasopressin on the 503B Bulks List.

[19] See Docket No. FDA–2015–N–3469, document no. FDA–2015–N–3469–0002.

[20] See, *e.g.,* labeling available as of the date of this notice at *https://www.accessdata.fda.gov/spl/data/32756b4e-a977-47ac-9620-0c1ed74d7606/32756b4e-a977-47ac-9620-0c1ed74d7606.xml* (ready-to-use) and *https://www.accessdata.fda.gov/spl/data/5444784f-fefe-4352-afd1-b4c487165f3a/5444784f-fefe-4352-afd1-b4c487165f3a.xml* (for dilution).

[21] Nicardipine hydrochloride is also approved as an oral capsule. See, *e.g.,* ANDA 074642.

[22] See NDAs 022276 and 019734.

and a related comment assert that it would be preferable to compound a drug product using a bulk drug substance than using an approved drug product that requires dilution. However, the nomination and comment do not take the position or provide support for the position that a bulk drug substance must be used to prepare the proposed concentrations of nicardipine hydrochloride. For example, the nomination does not indicate that the desired concentrations of nicardipine hydrochloride could not be prepared by diluting the approved drug product in a form that is suitable for patient administration. Nor is FDA aware of data or information suggesting this cannot be done. We note that the approved labeling of a nicardipine hydrochloride drug product directs the drug product to be diluted to a concentration within that range. We do not consider whether a benzoic acid-free nicardipine hydrochloride drug product must be compounded using the bulk drug substance because benzoic acid-free nicardipine hydrochloride product is FDA-approved at concentrations of 0.1 mg/mL and 0.2 mg/mL and because patients for whom these FDA-approved drug products may be medically unsuitable were not identified in section III.1.a. In sum, FDA finds no basis to conclude that drug products must be compounded using a bulk drug substance rather than the approved drug product.

2. Vasopressin

Vasopressin was nominated for inclusion on the 503B Bulks List to compound drug products that treat septic shock, post-cardiotomy shock, diabetes insipidus, and hypotension.[23] The proposed route of administration is intravenous; the proposed dosage form is injection. The nominators proposed a range of specific concentrations (0.1, 0.2, 0.4, and 1 units/mL (U/mL)) and concentrations above that range without identifying any specific concentration. This nominated bulk drug substance is the active ingredient of the FDA-approved drug VASOSTRICT (NDA 204485). VASOSTRICT is approved as a 20 U/mL intravenous infusion that, per its labeling, should be diluted with normal saline or 5 percent dextrose in water to either 0.1 U/mL or 1 U/mL for intravenous administration.[24]

VASOSTRICT is available in a multidose vial that contains the preservative agent chlorobutanol and in a single dose vial that does not contain chlorobutanol. The VASOSTRICT labeling includes a contraindication regarding chlorobutanol that applies to the chlorobutanol-containing product.[25] Because vasopressin is a component of an FDA-approved drug product, we considered whether (1) there is a basis to conclude that an attribute of each FDA-approved drug product containing vasopressin makes each one medically unsuitable to treat certain patients for a condition that FDA has identified for evaluation, and the vasopressin drug product proposed to be compounded is intended to address that attribute; and (2) whether the drug product proposed to be compounded must be compounded using a bulk drug substance.

a. Suitability of FDA-Approved Drug Product

The nominations propose vasopressin for the 503B Bulks List so that it can be used to compound drug product at various concentrations, some lower than undiluted VASOSTRICT and others higher. However, the nominations and the comments do not identify an attribute of VASOSTRICT that makes it medically unsuitable for patients and that the compounded products are intended to address.

The nomination that refers to products with a higher concentration than VASOSTRICT does not identify any data or information as to the need for a higher concentration than the approved product, nor does the nomination identify specific higher concentrations it proposes to compound. In addition, the nomination does not identify patients for whom a concentration at or below 20 U/mL is medically unsuitable and who would therefore require a higher concentration, and FDA is not aware of patients who would need concentrations above 20 U/mL.

Both nominations also propose to compound vasopressin at specific concentrations lower than undiluted VASOSTRICT. However, the proposed concentrations are within the range described in the labeling for the FDA-approved drug product, and the proposed route of administration (intravenous) is the same as that of VASOSTRICT. The nominations do not identify an attribute of the approved drug product that would make it medically unsuitable for patients or show that the compounded drug product would address that attribute.

Commenters on FDA's proposal not to include vasopressin on the 503B Bulks List assert that an attribute of VASOSTRICT that makes it medically unsuitable to treat patients is that it contains a preservative, chlorobutanol. Chlorobutanol-containing VASOSTRICT is contraindicated in patients who have an allergy or hypersensitivity to this excipient. However, the commenters fail to acknowledge that the preservative-free formulation of VASOSTRICT is also marketed and fail to explain why that formulation would be medically unsuitable for patients who have an allergy to chlorobutanol.

Accordingly, with respect to the vasopressin drug products proposed to be compounded, FDA finds no basis to conclude that an attribute of VASOSTRICT makes it medically unsuitable to treat certain patients.

b. Whether the Drug Product Must Be Compounded From a Bulk Drug Substance

As noted previously, the nominations propose to compound drug products containing vasopressin at concentrations that are lower than undiluted VASOSTRICT, but that are within the range of VASOSTRICT's final, post-dilution concentrations. The nominations do not take the position or provide support for the position that a bulk drug substance rather than the FDA-approved drug product must be used to prepare these lower concentrations. For example, the nominations do not explain, or even suggest, that the desired concentration of vasopressin cannot be prepared by diluting the approved drug product.[26] We do not consider whether a chlorobutanol-free vasopressin drug product must be compounded using the bulk drug substance because a chlorobutanol-free vasopressin product is FDA-approved and because patients for whom this FDA-approved drug product may be medically unsuitable were not identified in section III.2.a. In addition, in light of the analysis in section III.2.a. above, we do not

[23] See Docket No. FDA–2015–N–3469, documents No. FDA–2015–N–3469–0012 and –0023.

[24] The labeling as of the date of this notice is available at *https://www.accessdata.fda.gov/spl/data/4166e423-659e-4fe4-8a3c-2394434d00dd/4166e423-659e-4fe4-8a3c-2394434d00dd.xml.*

[25] The labeling states that VASOSTRICT is ''contraindicated in patients with known allergy or hypersensitivity to 8-L-arginine vasopressin or chlorobutanol.'' However, this contraindication is not applicable to the formulation of VASOSTRICT marketed without chlorobutanol. As described in the package insert, the VASOSTRICT 10 mL solution contains chlorobutanol, while the 1 mL solution does not.

[26] For example, the nomination does not take the position or provide support for a position that a drug product prepared by starting with the approved drug product would be unsuitable for patient administration. We also note that outsourcing facilities often prepare ready-to-use forms of drug products for healthcare practitioners by compounding (*e.g.,* diluting) approved drug products, including VASOSTRICT.

consider whether a bulk drug substance must be used to compound a vasopressin drug product at concentrations higher than 20 U/mL. In sum, FDA finds no basis to conclude that drug products must be compounded using a bulk drug substance rather than the approved drug product.

IV. Other Issues Raised in Nominations and Comments

The nominations for nicardipine hydrochloride and vasopressin and some comments state that there could be a benefit in the availability of drug products containing each of these bulk drug substances that do not require dilution prior to administration. We note first, with respect to nicardipine hydrochloride, that two ready-to-use nicardipine drug products are FDA-approved, and the comments do not identify patients for whom these products are medically unsuitable. More broadly, as explained above, when a bulk drug substance is a component of an approved drug, FDA asks whether there is a basis to conclude that an attribute of each approved drug product makes each one medically unsuitable to treat certain patients for their condition, an interpretation that protects patients and the integrity of the drug approval process. The nominations and comments do not show that the approved drug product, when not manufactured in the ready-to-use form, is medically unsuitable for certain patients. Nor do the nominations and comments establish that drug products in the relevant concentrations, including ready-to-use products, cannot be prepared from the approved nicardipine and vasopressin drug products.[27] Rather, they propose to compound a ready-to-use product from bulk drug substances to seek improved efficiency for prescribers or healthcare providers, or to address the possibility that the approved drug might be mishandled by a medical professional. That is not clinical need to compound a drug product using a bulk drug substance.

The nominations for nicardipine hydrochloride and vasopressin and some comments also include statements that these substances should be added to the 503B Bulks List because compounding from the bulk drug substance could help outsourcing facilities to address drug shortages and disruptions in supply of approved drugs intended for injection. As noted above, section 503B contains a separate provision for compounding from bulk drug substances to address a drug shortage, and we do not interpret the other price- and supply-related issues advanced by the nomination to be within the meaning of ''clinical need'' for compounding with a bulk drug substance.

V. Conclusion

For the reasons stated above, we find no clinical need for an outsourcing facility to compound using the bulk drug substances nicardipine hydrochloride and vasopressin and, therefore, we are not including nicardipine hydrochloride and vasopressin on the 503B Bulks List.

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03810 Filed 3–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0280]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 3, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0396. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Financial Disclosure by Clinical Investigators

OMB Control Number 0910–0396—Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Table 1 of this document shows information that is the basis of the estimated number of respondents in tables 2 through 4.

TABLE 1—ESTIMATED NUMBER OF APPLICATIONS, CLINICAL TRIALS, AND INVESTIGATORS SUBJECT TO THE REGULATION BY TYPE OF APPLICATION [1]

Application type	Total number of applications	Number of applications affected	Number of trials	Number of investigators
Drugs:				

[27] With respect to vasopressin specifically, a comment states that vasopressin cannot be produced in ready-to-use form because the approved drug product is labeled with an in-use time of 18 hours room temperature or 24 hours refrigerated once diluted. In contrast, the commenter says that it could compound a ''pre-diluted'' drug product from bulk vasopressin with a beyond-use-date (BUD) of 60 days. We note that, in accordance with CGMP provisions, outsourcing facilities can conduct stability studies on vasopressin compounded using the approved drug product to assign a BUD based on data.

TABLE 1—ESTIMATED NUMBER OF APPLICATIONS, CLINICAL TRIALS, AND INVESTIGATORS SUBJECT TO THE REGULATION BY TYPE OF APPLICATION [1]—Continued

Application type	Total number of applications	Number of applications affected	Number of trials	Number of investigators
New drug application (NDA), new molecular entity (NME)	35	26	3 to 10	3 to 100.
NDA nonNME:				
NDA efficacy supplement	173	86	1 to 3	10 to 30.
Abbreviated new drug application (ANDA)	1,152	250	1.1	2.
ANDA supplement	6,774	383	1	2.
Biologics:				
Biologics license application (BLA)	22	19	3 to 10	3 to 100.
BLA efficacy supplement	16	14	1 to 3	10 to 30.
Medical Devices:				
Premarket approval (PMA)	48	48	1 to 3	10 to 20.
PMA supplement	23	23	1 to 3	3 to 10.
Reclassification devices	3	1	1	3 to 10.
510(k)	4,000	200	1	3 to 10.

[1] Source: Agency estimates.

In the **Federal Register** of September 27, 2018 (83 FR 48819), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, however, it was not responsive to the four collection of information topics solicited and therefore this comment will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

Reporting Burden

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

FDA estimates that almost all applicants submit a certification statement under § 54.4(a)(1) and (a)(2). Preparation of the statement using Form FDA 3454 should require no more than 1 hour per study. The number of respondents is based on the estimated number of affected applications.

When certification is not possible and disclosure is made using Form FDA 3455, the applicant must describe, under § 54.4(a)(3), the financial arrangements or interests and the steps that were taken to minimize the potential for bias in the affected study. As the applicant would be fully aware of those arrangements and the steps taken to address them, describing them will be straightforward. The Agency estimates that it will take about 5 hours to prepare this narrative. Based on our experience with this collection, FDA estimates that approximately 10 percent of the respondents with affected applications will submit disclosure statements.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification—54.4(a)(1) and (a)(2)—Form FDA 3454	1,050	1	1,050	1	1,050
Disclosure—54.4(a)(3)—Form FDA 3455	105	1	105	5	525
Total					1,575

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping Burden

Under § 54.6, the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for 2 years after the date of approval of the applications. Sponsors of covered studies maintain many records regarding clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates that an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigator's file.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Recordkeeping—54.6	1,050	1	1,050	0.25	263

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Third-Party Disclosure Burden

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that the time required for this task may range from 5 to 15 minutes; we used the mean, 10 minutes, for the average burden per disclosure. The number of respondents is the sum of the number of affected applications multiplied by the mean of the estimated number of investigators for each application type (rounded) (see table 1 of this document).

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
54.4(b)—Clinical Investigators	7,894	1	7,894	0.17	1,342

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 222 hours and a corresponding increase of 893 responses/records. We attribute this adjustment to an increase in the number of affected applications and the number of investigators. No program changes were made.

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03828 Filed 3–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1067]

Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry entitled ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes policies that FDA intends to use in evaluating bulk drug substances nominated for use in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for inclusion on the list of bulk drug substances that can be used in compounding under section 503B.

DATES: The announcement of the guidance is published in the **Federal Register** on March 4, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–1067 for ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked

as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Section 503B (21 U.S.C. 353b), added to the FD&C Act by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and section 582 (21 U.S.C. 360eee-1) (concerning drug supply chain security requirements). One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility does not compound drug products using a bulk drug substance unless either: (1) It appears on a list established by the Secretary of Health and Human Services identifying bulk drug substances for which there is a clinical need (see section 503B(a)(2)(A)(i) of the FD&C Act) (503B Bulks List) or (2) the drug compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing (see section 503B(a)(2)(A)(ii) of the FD&C Act).

This guidance addresses FDA policies for developing the 503B Bulks List, including the Agency's interpretation of the phrase ''bulk drug substances for which there is a clinical need,'' as it is used in section 503B of the FD&C Act. The guidance also addresses the factors and processes by which the Agency intends to evaluate and list bulk drug substances.

In the **Federal Register** of March 26, 2018 (83 FR 12952), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period ended on May 25, 2018. FDA received approximately 60 comments on the draft guidance. In response to received comments or on its own initiative, FDA made certain changes to the guidance. For example, FDA has further explained how Congress' limitation on bulk drug substances that can be used in compounding under section 503B helps to preserve the integrity of the new drug approval process and identified the process to request that FDA add or remove a bulk drug substance from the 503B Bulks List after the Agency has made a final determination with respect to that substance in the **Federal Register**.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov*.

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03807 Filed 3–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments To Inform Development of a National Youth Sports Strategy

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) solicits written comments from the public on specific topics and questions that will inform the development of the National Youth Sports Strategy.

DATES: Written comments will be accepted through 11:59 p.m. E.T. on April 1, 2019.

ADDRESSES: Written public comments will be accepted via email. Instructions for submitting comments are available on the internet at *https://fitness.gov.*

FOR FURTHER INFORMATION CONTACT: Katrina L. Piercy, Ph.D., R.D., Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health (OASH), HHS; 1101 Wootton Parkway, Suite LL–100; Rockville, MD 20852; Telephone: (240) 453–8280. Email: *odphpinfo@hhs.gov*.

SUPPLEMENTARY INFORMATION: Executive Order 13824 directs the development of a National Strategy on Youth Sports and outlines the key pillars that the strategy will address. The Office of Disease Prevention and Health Promotion and the President's Council on Sports, Fitness & Nutrition are leading the development of this strategy.

Key Pillars of Youth Sports Strategy

1. Increase awareness of the benefits of participation in sports and regular physical activity, as well as the importance of good nutrition;
2. Promote private and public sector strategies to increase participation in sports, encourage regular physical activity, and improve nutrition;
3. Develop metrics that gauge youth sports participation and physical activity to inform efforts that will

improve participation in sports and regular physical activity among young Americans; and

4. Establish a national and local strategy to recruit volunteers who will encourage and support youth participation in sports and regular physical activity, through coaching, mentoring, teaching, or administering athletic and nutritional programs.

Written Public Comments: Written comments to inform the development of the strategy are encouraged from the public and will be accepted via email until 11:59 p.m. E.T. April 1, 2019. Instructions for submitting comments are available at *https://fitness.gov*. HHS requests that commenters respond to the questions posed on *https://fitness.gov*. A subsequent public comment period will open this summer to provide comments on the draft strategy report.

Dated: February 19, 2019.

Donald Wright,

Deputy Assistant Secretary for Health Disease Prevention and Health Promotion.

[FR Doc. 2019–03788 Filed 3–1–19; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee 2019 Schedule

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: 2019 public meeting dates of the Health Information Technology Advisory Committee.

SUMMARY: The Health Information Technology Advisory Committee (HITAC) was established in accordance with section 4003(e) of the 21st Century Cures Act and the Federal Advisory Committee Act. The HITAC, among other things, identifies priorities for standards adoption and makes recommendations to the National Coordinator for Health Information Technology (National Coordinator). The HITAC will hold public meetings throughout 2019. See list of public meetings below.

FOR FURTHER INFORMATION CONTACT: Lauren Richie, Designated Federal Officer, at *Lauren.Richie@hhs.gov,* or (202) 205–7674.

SUPPLEMENTARY INFORMATION: Section 4003(e) of the 21st Century Cures Act (Pub. L. 114–255) establishes the Health Information Technology Advisory Committee (referred to as the ''HITAC''). The HITAC will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

Composition

The HITAC is comprised of at least 25 members, of which:

- No fewer than 2 members are advocates for patients or consumers of health information technology;
- 3 members are appointed by the HHS Secretary
  - 1 of whom shall be appointed to represent the Department of Health and Human Services and
  - 1 of whom shall be a public health official;
- 2 members are appointed by the majority leader of the Senate;
- 2 members are appointed by the minority leader of the Senate;
- 2 members are appointed by the Speaker of the House of Representatives;
- 2 members are appointed by the minority leader of the House of Representatives; and
- Other members are appointed by the Comptroller General of the United States.

Members will serve for one-, two-, or three-year terms. All members may be reappointed for subsequent three-year terms. Each member is limited to two three-year terms, not to exceed six years of service. After establishment, members shall be appointed for a three-year term. Members serve without pay, but will be provided per-diem and travel costs for committee services.

Recommendations

The HITAC recommendations to the National Coordinator are publicly available at *https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it.*

Public Meetings

The schedule of meetings to be held in 2019 is as follows:

- February 20, 2019 from approximately 9:30 a.m.. to 2:30 p.m./Eastern Time (virtual meeting)
- March 19–20, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time each day at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008
- April 10, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008
- April 25, 2019 from approximately 9:30 a .m. to 2:30 p.m./Eastern Time (virtual meeting)
- May 13, 2019 from approximately 9:30 a .m. to 2:30 p.m./Eastern Time (virtual meeting)
- June 19, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- September 17, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time at the Key Bridge Marriott Hotel, 1401 Lee Highway, Arlington, Virginia 22209
- October 16, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- November 13, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)

All meetings are open to the public. Additional meetings may be scheduled as needed. For web conference instructions and the most up-to-date information, please visit the HITAC calendar on the ONC website, *http://www.healthit.gov/FACAS/calendar.*

Contact Person for Meetings: Lauren Richie, *lauren.richie@hhs.gov* . A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Please email Lauren Richie for the most current information about meetings.

Agenda: As outlined in the 21st Century Cures Act, the HITAC will develop and submit recommendations to the National Coordinator on the topics of interoperability, privacy and security, and patient access. In addition, the committee will also address any administrative matters and hear periodic reports from ONC. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its website prior to the meeting, the material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's website after the meeting, at *http://www.healthit.gov/hitac.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person prior to the meeting date. An oral public comment period will be scheduled at each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled public comment period, ONC will take written comments after the meeting.

Persons attending ONC's HITAC meetings are advised that the agency is not responsible for providing wireless access or access to electrical outlets.

ONC welcomes the attendance of the public at its HITAC meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lauren Richie at least seven (7) days in advance of the meeting.

Notice of these meetings are given under the Federal Advisory Committee Act (Pub. L. No. 92–463 , 5 U.S.C., App. 2).

Dated: February 26, 2019.

Lauren Richie,

Office of Policy, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2019–03793 Filed 3–1–19; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Cooperative Agreement With the Pan American Health Organization

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services (HHS) intends to provide a Single Source Three Year Cooperative Agreement to the Pan American Health Organization (PAHO). The Cooperative Agreement will continue to improve operational capabilities to provide timely, coordinated, and quality medical response to disasters in the Americas region by supporting the WHO Emergency Medical Teams (EMT) Initiative. The collaboration between ASPR and PAHO will focus on supporting PAHO's strategy to develop and train national emergency medical teams with a set of global standards in each country in the region to ensure they can respond to emergencies within their own borders. PAHOs regional strategy for the EMT Initiative concentrates on building emergency medical teams domestically, for each country in the region, to ensure they can respond to emergencies within their own borders first, thereby reducing dependence on U.S. medical assets/capabilities. The total proposed cost of the Single Source Cooperative Agreement is not to exceed $1 million over the three-year life of the Cooperative Agreement.

DATES:

Project Period: The period of performance is from September 30, 2019 to September 30, 2022.

Award Amount: Estimate $1 million.

FOR FURTHER INFORMATION CONTACT:

Maria Marinissen—*Maria .Marinissen@hhs.gov,* (202) 205–4214.

Michael Guterbock—*Michael .Guterbock@hhs.gov,* (202) 701–5631.

SUPPLEMENTARY INFORMATION: The Office of the Assistant Secretary for Preparedness and Response (ASPR), International Policy Branch is the program office for this Cooperative Agreement.

Single Source Justification: Founded in 1902, PAHO, based in Washington DC, is an international public health agency working to improve the health and living standards of the people of the Americas Region. It is part of the United Nations system, serving as the Regional Office for the Americas of the World Health Organization (WHO). PAHO is uniquely placed to enhance the medical response capabilities of countries in the Americas Region. The partnership between ASPR and PAHO gives ASPR the ability to shape critical outcomes of the EMT Initiative regionally, and helps inform a timely HHS decision about whether and how to participate in the next generation of international response systems. Although no USG emergency medical response team is part of the EMT, multiple U.S. based non-governmental organizations have been certified or are in the process of certification. It is critical that HHS/ASPR maintains visibility on U.S. based EMTs for both situational awareness and coordination purposes during emergency responses abroad or domestically. Furthermore, increasing the regional disaster response capacities may help alleviate the burden on U.S. resources and assets every time our country is called to provide assistance in the region. Importantly, since there are no self-sufficient USG medical teams ready to deploy internationally and registered in PAHO's roster of EMTs, making sure countries have their own teams may significantly decrease requests for assistance from the USG and the potential for burden to U.S. assets.

The three-year scope of work of the renewed cooperative agreement will build upon the successes of past activities, including the following overarching objectives:

- Development of SOPs and plans for emergency and disaster response of pre-hospital emergency services and EMTs, and the development of tools/guidelines for the optimization of the delivery of clinical care during emergencies.
- Provision of technical support to develop national mechanisms for the registration and mapping of local emergency medical teams for domestic response; mentoring for the creation and operation of EMTs; technical support to national EMTs to ensure self-sufficiency and provision of timely and quality clinical care.
- Development and strengthening of nationally-led health emergency coordination mechanisms (Health EOCs) and technical support to countries to establish or strengthen their health EOCs.
- Integration of national coordination mechanisms (CICOM) including guidelines and operational support for the creation, management and implementation of national CICOM.
- Strengthening of regional health emergency surge capacity including capacity building of national experts in critical areas of emergency coordination, health services, surveillance, logistics, damage and needs assessment, risk communication, etc.

Please submit an inquiry via the ASPR Program Contact: Michael Guterbock, MPH, *Michael.Guterbock@hhs.gov*, (202) 701–5631.

Authority: Section 301 of the Public Health Service (PHS) Act.

Dated: February 25, 2019.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2019–03842 Filed 3–1–19; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Cooperative Agreement With the Institut Pasteur International Network

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services intends to provide a Single Source Five Year Cooperative Agreement to *Institut Pasteur* International Network (IPIN) through the Pasteur Foundation. The Cooperative Agreement will support

continue to guide and support public health capacities to prepare for, detect, and respond to potential public health emergencies caused by human influenza viruses, zoonotic diseases, and other emerging infectious diseases with pandemic potential in West and Central Africa, and Southeast Asia to support the health security of the United States. The total proposed cost of the Single Source Cooperative Agreement is not to exceed $5 million over the five-year life of the Cooperative Agreement.

DATES:

Project Period: The period of performance is from September 30, 2019 to September 30, 2024.

Award Amount: Estimate $5 million.

FOR FURTHER INFORMATION CONTACT:

Maria Marinissen—*Maria .Marinissen@hhs.gov,* (202) 205–4214.

Robin Moudy—*Robin.Moudy@ hhs.gov,* 202–260–2105.

SUPPLEMENTARY INFORMATION: The Office of the Assistant Secretary for Preparedness and Response (ASPR), International Policy Branch is the program office for this Cooperative Agreement:

Single Source Justification: Founded in 1887, *Institut Pasteur,* based in Paris, has an international research network with 33 institutes globally committed to advancing science, medicine and public health, with especially unmatched reach in the Francophone world. This partnership between ASPR and IPIN gives ASPR access to information and the ability to build international partner capacity to prepare for, detect, and respond to potential public health emergencies caused by human influenza viruses, zoonotic diseases, and other emerging infectious diseases with pandemic potential in West and Central Africa, and Southeast Asia that could have an severe impact on the health security of the United States and its citizens.

The focus will be on countries in West and Central Africa, Madagascar, and Southeast Asia (Cambodia) where IPIN is the primary laboratory partner of the host government, although supported partnerships may extend beyond those countries and regions. Prior to each annual award, affiliated laboratories will submit their proposed scope of work, which may be adjusted over the course of the year based on changing needs and priorities or other exigent circumstances, such as a critical outbreak response.

The five-year scope of work of the renewed cooperative agreement will build upon the successes of past activities, including the following overarching objectives:

- Facilitate public health emergency planning, rapid epidemiologic responses, public health event assessment pursuit to the IHR, international data or event reporting as determined by the host government, and assist with emergency management where needed;
- Ensure One Health coordination with the WHO, the World Organization for Animal Health (OIE), national human, animal, and environmental health agencies, and others as needed to address zoonotic disease threats.
- System in place for medical countermeasures distribution during a public health emergency and integrating vaccine coverage as part of national program;
- Interoperable, interconnected, electronic real-time reporting system with emergency operation centers, and risk communication processes in place;
- Improve the quality and scale of public health surveillance, national epidemiologic data, and infectious diseases diagnostics;
- Develop, produce, acquire, and/or deploy novel infectious disease surveillance assays and clinical diagnostic tests during an outbreak;
- Strengthen laboratory biosafety and biosecurity systems, including the ability to scale-up in response to an epidemic caused by a highly dangerous pathogen;
- Real-time reporting system, and risk communication processes in place.

Please submit an inquiry via the ASPR Program Contact: Dr. Robin Moudy, *Robin.Moudy@hhs.gov*, 202–260–2105.

Authority: Sections 301 and 307 of the Public Health Service Act (42 U.S.C. 241, 242l).

Dated: February 25, 2019.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2019–03846 Filed 3–1–19; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–18 –002: Understanding Skeletal Effects of Type 1 Diabetes (R01).

Date: March 15, 2019.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *jerkinsa@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Urological Clinical Small Business Applications.

Date: March 22, 2019.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–4721, *ryan.morris@nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK–RC2 Application Review.

Date: April 2, 2019.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7023, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 26, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03751 Filed 3–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–17–031: Characterization and Discovery of Novel Autoantigens and Epitopes in Type 1 Diabetes (R01).

Date: March 25, 2019.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–7682, *campd@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 26, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03805 Filed 3–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Mental Health Services Member Conflict.

Date: March 22, 2019.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301–451–2356, *gavinevanskm@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Career Enhancement Awards.

Date: March 29, 2019.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Aileen Schulte, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: February 26, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03806 Filed 3–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Member Conflict SEP.

Date: March 26, 2019.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20892.

Contact Person: Christiane M. Robbins, Scientific Review Officer, Scientific Review Branch (SRB), DER, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2121A, Bethesda, MD 20817, 301–451–4989, *crobbins@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Contraception Research Centers Program (U54 Clinical Trial Optional).

Date: April 29–30, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase, Pavilion 4300 Military Road NW, Washington, DC 20015.

Contact Person: Joanna Kubler-Kielb, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Bethesda, MD 20817, 301–435–6916, *kielbj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: February 26, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–03752 Filed 3–1–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council (NAC) will meet on March 28, 2019, 1:00 p.m.–4:30 p.m. (EDT).

The meeting is open and will include consideration of minutes from the SAMHSA CSAT NAC meeting of August 1, 2018; the Director's Report; updates from the Division Directors, discussions on recovery housing, and discussions expanding access to Medication-Assisted Treatment.

The meeting will be held via WebEx and telephone only. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person on or before March 20, 2019. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact person on or before March 20, 2019. Five minutes will be allotted for each presentation.

This is an open public meeting that will be conducted via WebEx and telephone. Registration is required to participate during this meeting. To attend virtually, or to obtain the call-in number and access code, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register on-line at *http://snacregister.samhsa.gov/MeetingList.aspx,* or communicate with the CSAT National Advisory Council Designated Federal Officer; Tracy Goss (see contact information below). Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee website at *http://www.samhsa.gov/about-us/advisory-councils/csat-national-advisory-council* or by contacting the CSAT National Advisory Council Designated Federal Officer; Tracy Goss (see contact information below).

Council Name: SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

Date/Time/Type: March 28, 2019, 1:00 p.m.–4:30 p.m. EDT, Open.

Place: SAMHSA, 5600 Fishers Lane, Rockville, Maryland 20857.

Contact: Tracy Goss, Designated Federal Officer, CSAT National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail). Telephone: (240) 276–0759. Fax: (240) 276–2252. Email: *tracy.goss@samhsa.hhs.gov.*

Dated: February 26, 2019.

Carlos Castillo,

Committee Management Officer, SAMHSA.

[FR Doc. 2019–03743 Filed 3–1–19; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of SGS North America, Inc. (East Alton, IL), as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of SGS North America, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that SGS North America, Inc. (East Alton, IL), has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes for the next three years as of September 5, 2018.

DATES: SGS North America, Inc., was accredited and approved as a commercial gauger and laboratory as of September 5, 2018. The next triennial inspection date will be scheduled for September 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that SGS North America, Inc., 300 George St., East Alton, IL 62024, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. SGS North America, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API Chapters	Title
3	Tank gauging.
7	Temperature Determination.
8	Sampling.
12	Calculations.
17	Maritime Measurements.

SGS North America, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the

website listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*.

Dated: February 26, 2019.

Patricia Hawes Coleman,

Acting Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2019–03732 Filed 3–1–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2008–0010]

Board of Visitors for the National Fire Academy

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Committee management; Notice of open Federal Advisory Committee meeting.

SUMMARY: The Board of Visitors for the National Fire Academy (Board) will meet via teleconference on Tuesday, March 19, 2019. The meeting will be open to the public.

DATES: The meeting will take place on Tuesday, March 19, 2019, 1:30 to 3:30 p.m. Eastern Daylight Time. Please note that the meeting may close early if the Board has completed its business.

ADDRESSES: Members of the public who wish to participate in the teleconference should contact Deborah Gartrell-Kemp as listed in the **FOR FURTHER INFORMATION CONTACT** section by close of business March 15, 2019, to obtain the call-in number and access code for the March 19th meeting. For more information on services for individuals with disabilities or to request special assistance, contact Debbie Gartrell-Kemp as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Board as listed in the **SUPPLEMENTARY INFORMATION** section. Participants seeking to have their comments considered during the meeting should submit them in advance or during the public comment segment. Comments submitted up to 30 days after the meeting will be included in the public record and may be considered at the next meeting. Comments submitted in advance must be identified by Docket ID FEMA–2008–0010 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: FEMA-RULES@fema.dhs.gov.* Include the docket number in the subject line of the message.
- *Mail/Hand Delivery:* Deborah Gartrell-Kemp, 16825 South Seton Avenue, Emmitsburg, Maryland 21727, post marked no later than March 11, 2019.

Instructions: All submissions received must include the words ''Federal Emergency Management Agency'' and the Docket ID for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the National Fire Academy Board of Visitors, go to *http://www.regulations.gov,* click on ''Advanced Search,'' then enter ''FEMA–2008–0010'' in the ''By Docket ID'' box, then select ''FEMA'' under ''By Agency,'' and then click ''Search.''

FOR FURTHER INFORMATION CONTACT: *Alternate Designated Federal Officer:* Kirby E. Kiefer, telephone (301) 447–1117, email *Kirby.Kiefer@fema.dhs.gov.*

Logistical Information: Deborah Gartrell-Kemp, telephone (301) 447–7230, email *Deborah.GartrellKemp@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix.

Purpose of the Board

The purpose of the Board is to review annually the programs of the National Fire Academy (Academy) and advise the Administrator of the Federal Emergency Management Agency (FEMA), through the United States Fire Administrator, on the operation of the Academy and any improvements therein that the Board deems appropriate. In carrying out its responsibilities, the Board examines Academy programs to determine whether these programs further the basic missions that are approved by the Administrator of FEMA, examines the physical plant of the Academy to determine the adequacy of the Academy's facilities, and examines the funding levels for Academy programs. The Board submits a written annual report through the United States Fire Administrator to the Administrator of FEMA. The report provides detailed comments and recommendations regarding the operation of the Academy.

Agenda

On Tuesday, March 19, 2019, there will be four sessions, with deliberations and voting at the end of each session as necessary: The board will discuss the following:

1. USFA Data, Research, Prevention and Response.

2. Deferred maintenance and capital improvements on the National Emergency Training Center campus and Fiscal Year 2019 Budget Request/Budget Planning.

3. The Board will deliberate and vote on recommendations on Academy program activities, including:

- An update on the Executive Fire Officer Program which is being revised to include reactions and calls from students about the changes.
- The Executive Fire Officer Program Symposium that will be held April 26–28, 2019.
- The Fire and Emergency Services Higher Education Recognition Program—Up-date.
- Curriculum Development and Revision Updates for NFA Courses.
- State Training Delivery Update; Enfranchisement and State Partners.
- Distance Learning Program Update (Mediated and Self-Study).
- NFA Technology Workgroup Initiative.
- Admissions Update for the Semester.
- Staffing Update.
- There will also be an update on the Board of Visitors Subcommittee Groups for the Professional Development Initiative Update and the National Fire Incident Report System.

There will be a 10-minute comment period after each agenda item and each speaker will be given no more than 2 minutes to speak. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact Deborah Gartrell-Kemp to register as a speaker. Meeting materials will be posted at *https://www.usfa.fema.gov/training/nfa/about/bov.html* by March 15, 2019.

Dated: February 19, 2019.

Tonya L. Hoover,

Superintendent, National Fire Academy, United States Fire Administration, Federal Emergency Management Agency.

[FR Doc. 2019–03794 Filed 3–1–19; 8:45 am]

BILLING CODE 9111–45–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–ES–2018–N163; FXES11130500000–190–FF05E00000]

Endangered and Threatened Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before April 3, 2019.

ADDRESSES: Use one of the following methods to request documents or submit comments. Requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* TE123456):

- *Email: permitsR5ES@fws.gov.*
- *U.S. Mail:* Abby Gelb, Ecological Services, U.S. Fish and Wildlife Service, 300 Westgate Center Dr. Hadley, MA 01035.

FOR FURTHER INFORMATION CONTACT: Abby Gelb, 413–253–8212 (phone), or *permitsR5ES@fws.gov* (email). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered or threatened under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of ''take'' includes such activities as pursuing, harassing, trapping, capturing, or collecting in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

We invite local, State, and Federal agencies; Tribes; and the public to comment on the following applications.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
TE18372D ..	U.S. Fish and Wildlife Service, Hadley, MA.	*Amphibians:* Shenandoah salamander (*Plethodon shenandoah*); *Birds:* Piping plover (*Charadrius melodus*), Red-cockaded woodpecker (*Picoides borealis*), Roseate tern (*Sterna dougallii dougallii*); *Fish:* Atlantic salmon (*Salmo salar*), Diamond darter (*Crystallaria cincotta*), Duskytail darter (*Etheostoma percnurum*), Maryland darter (*Etheostoma sellare*), Roanoke logperch (*Percina rex*); *Invertebrates:* American burying beetle (*Nicrophorus americanus*), Appalachian monkeyface pearlymussel (*Quadrula sparsa*), Birdwing pearlymussel (*Lemiox rimosus*), Clubshell mussel (*Pleurobema clava*), Cracking pearlymussel (*Hemistena lata*), Cumberland bean pearlymussel (*Villosa trabalis*), Cumberland monkeyface pearlymussel (*Quadrula intermedia*), Cumberlandian combshell mussel (*Epioblasma brevidens*), Dromedary pearlymussel (*Dromus dromas*), Dwarf wedgemussel (*Alasmidonta heterodon*), Fanshell mussel (*Cyprogenia stegaria*), Fine-rayed pigtoe mussel (*Fusconaia cuneolus*), Fluted kidneyshell mussel (*Ptychobranchus subtentum*), Green blossom pearlymussel (*Epioblasma torulosa gubernaculum*), Guyandotte River crayfish (*Cambarus veteranus*), Hay's Spring amphipod (*Stygobromus hayi*), James spinymussel (*Pleurobema collina*), Karner blue butterfly (*Lycaeides melissa samuelis*), Lee County cave isopod (*Lirceus usdagalun*), Littlewing pearlymussel (*Pegias fabula*), Mitchell's satyr butterfly (*Neonympha mitchellii mitchellii*), Northern riffleshell mussel (*Epioblasma torulosa rangiana*), Orangefoot pimpleback pearlymussel (*Plethobasus cooperianus*), Oyster mussel (*Epioblasma capsaeformis*), Pink mucket pearlymussel (*Lampsilis abrupta*), Purple bean mussel (*Villosa perpurpurea*), Rayed bean mussel (*Villosa fabalis*), Ring pink mussel (*Obovaria retusa*), Rough pigtoe mussel (*Pleurobema plenum*), Rough rabbitsfoot (*Quadrula cylindrica strigillata*), Rusty patched bumble bee (*Bombus affinis*), Sheepnose mussel (*Plethobasus cyphyus*), Shiny pigtoe mussel (*Fusconaia cor*), Slabside pearlymussel (*Pleuronaia dolabelloides*), Snuffbox mussel (*Epioblasma triquetra*), Spectaclecase mussel (*Cumberlandia monodonta*), Spruce-fir moss spider (*Microhexura montivaga*), Tan riffleshell mussel (*Epioblasma florentina walkeri*), Tubercled blossom pearlymussel (*Epioblasma torulosa torulosa*), Virginia fringed mountain snail (*Polygyriscus virginianus*);	CT, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VA, VT, WV, DC.	Survey, capture, collect, handle, transport, release, selective euthanize, propagate, translocate, reintroduce.	Harass, harm, pursue, wound, lethal collection, trap, capture, or collect.	Renew.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
		Mammals: Carolina northern flying squirrel (*Glaucomys sabrinus coloratus*), Gray bat (*Myotis grisescens*), Gray wolf (*Canis lupus*), Indiana bat (*Myotis sodalis*), Virginia big-eared bat (*Corynorhinus townsendii virginianus*); *Reptiles:* Hawksbill sea turtle (*Eretmochelys imbricata*), Kemp's ridley sea turtle (*Lepidochelys kempii*), Leatherback sea turtle (*Dermochelys coriacea*), Northern red-bellied turtle (*Pseudemys rubriventris*); *Plants:* American chaffseed (*Schwalbea americana*), Canby's dropwort (*Oxypolis canbyi*), Furbish lousewort (*Pedicularis furbishiae*), Harperella (*Ptilimnium nodosum*), Jesup's milk-vetch (*Astragalus robbinsii* var. *jesupi*), Michaux's sumac (*Rhus michauxii*), Northeastern bulrush (*Scirpus ancistrochaetus*), Peter's Mountain mallow (*Iliamna corei*), Roan Mountain bluet (*Hedyotis purpurea* var. *montana*), Rock gnome lichen (*Gymnoderma lineare*), Running buffalo clover (*Trifolium stoloniferum*), Sandplain gerardia (*Agalinis acuta*), Schweinitz's sunflower (*Helianthus schweinitzii*), Shale barren rock cress (*Arabis serotina*), Small-anthered bittercress (*Cardamine micranthera*), Smooth coneflower (*Echinacea laevigata*).				
TE01086D ..	Aquatic Wildlife Conservation Center, Virginia Department of Game and Inland Fisheries, Marion, VA.	Appalachian monkeyface *(Quadrula sparsa),* Birdwing pearlymussel *(Lemiox rimosus),* Cracking pearlymussel *(Hemistena lata),* Cumberland monkeyface *(Quadrula intermedia),* Cumberlandian combshell *(Epioblasma brevidens),* Dromedary pearlymussel *(Dromus dromas),* Fanshell *(Cyprogenia stegaria),* Finerayed pigtoe *(Fusconaia cuneolus),* Fluted kidneyshell *(Ptychobranchus subtentum),* Green blossom *(Epioblasma torulosa gubernaculum),* Littlewing pearlymussel *(Pegias fabula),* Oyster mussel *(Epioblasma capsaeformis),* Pink mucket *(Lampsilis abrupta),* Purple bean *(Villosa perpurpurea),* Rough pigtoe *(Pleurobema planum),* Rough rabbitsfoot *(Quadrula cylindrica strigillata),* Sheepsnose Mussel *(Plethobasus cyphyus),* Shiny pigtoe *(Fusconaia cor),* Slabside Pearlymussel *(Pleuronaia dolabelloides),* Snuffbox mussel *(Epioblasma triquetra),* Spectaclecase mussel *(Cumberlandia monodonta),* Tan riffleshell *(Epioblasma florentina walkeri)*	VA, TN	Collect adults as broodstock and ark populations; propagate; release juveniles and adults.	Capture, collect, transport, propagate, release, reintroduce.	Renew.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Martin Miller,

Chief, Division of Endangered Species, Ecological Services, Northeast Region.

[FR Doc. 2019–03779 Filed 3–1–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Selection Procedures for Reviewing Applications Filed by Employers Seeking Temporary Employment of H–2B Foreign Workers in the United States

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor's (Department's or DOL's) Office of Foreign Labor Certification (OFLC) is making this announcement to inform employers and other interested stakeholders of how H–2B *Applications for Temporary Employment Certification,* Form ETA–9142B, filed by employers on or after July 3, 2019, will be assigned to staff for review. The Department believes these procedural changes will provide for fairer and more orderly assignment and review of applications. The Department is seeking public comments on these procedural changes.

DATES: To be ensured for consideration, comments must be submitted in writing on or before April 3, 2019. OFLC will review all of the comments received and will make any changes it determines are appropriate prior to July 3, 2019. The new procedural changes are applicable on July 3, 2019.

ADDRESSES: You may submit comments by one of the following methods:

Mail and hand delivery/courier: Submit comments to Thomas M. Dowd, Deputy Assistant Secretary, Employment and Training Administration, Box PPII 12–200, 200 Constitution Avenue NW, Washington, DC 20210. Due to security-related concerns, there may be a significant delay in the receipt of submissions by United States Mail. You must consider this when preparing to meet the deadline for submitting comments.

Email: Submit comments to *H2BReform.Comments@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas M. Dowd, Deputy Assistant Secretary, Employment and Training Administration, Department of Labor,

Box #12–200, 200 Constitution Ave. NW, Washington, DC 20210, Telephone: (202) 693–2772 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

Statutory Background

The Immigration and Nationality Act (INA), 8 U.S.C. 1101, *et seq.,* establishes the H–2B nonimmigrant classification for a nonagricultural temporary worker ''having a residence in a foreign country which he has no intention of abandoning who is coming temporarily to the United States to perform . . . temporary [non-agricultural] service or labor if unemployed persons capable of performing such service or labor cannot be found in this country.'' 8 U.S.C. 1101(a)(15)(H)(ii)(b). The Secretary of the Department of Homeland Security (DHS), in administering the H–2B program, may grant an employer's petition for an otherwise eligible H–2B nonimmigrant worker ''after consultation with appropriate agencies of the Government.'' 8 U.S.C. 1184(c)(1). The Secretary of DHS also may delegate to ''any employee of the United States, with the consent of the head of the applicable Department or other independent establishment, . . . any of the powers, privileges, or duties conferred or imposed'' on DHS under the INA. 8 U.S.C. 1103(a)(6); *see also* 8 CFR 2.1. DHS regulations provide that an H–2B petition for temporary employment in the United States must be accompanied by an approved Temporary Labor Certification (TLC) from DOL. 8 CFR 214.2(h)(6)(iii)(A), (iv)(A). Pursuant to and in accordance with the above authorities, the TLC serves as DHS's consultation with DOL to determine the question of whether a qualified U.S. worker is available to fill the petitioning H–2B employer's job opportunity and whether a foreign worker's employment in the job opportunity will adversely affect the wages or working conditions of similarly-employed U.S. workers. *See* 8 CFR 214.2(h)(6)(iii)(A), (D).

In order to advise DHS on the availability of U.S. workers and the potential for adverse effect on the wages and working conditions of similarly-employed U.S. workers, OFLC provides consultation to DHS through issuance of TLCs, in accordance with 8 U.S.C. 1103(a) and 1184(c). *See* 8 CFR 214.2(h)(6)(iii)(A), (D). DOL and DHS have jointly issued regulations that govern the standards and procedures applicable to OFLC's issuance of TLCs under the H–2B program. *See* 20 CFR 655 subpart A. The regulations at 20 CFR 655 subpart A require employers seeking H–2B temporary labor certification to, among other things, file an *Application for Temporary Employment Certification* and all supporting documentation, hereinafter referred to as the ''H–2B application,'' required by this subpart to secure a TLC from the Department.

The INA sets the annual number of aliens who may be issued H–2B visas or otherwise provided H–2B nonimmigrant status to perform temporary nonagricultural work at 66,000, to be distributed semi-annually, not to exceed 33,000 in the first half of the Federal Government's fiscal year beginning on October 1 of each year and the remainder during the second half of the Federal Government's fiscal year beginning on April 1 of the subsequent calendar year. *See* 8 U.S.C. 1184(g)(1)(B), (g)(10). If insufficient petitions are approved to use all 66,000 H–2B slots in a given fiscal year, the unused slots are not carried over for petition approvals in the next fiscal year.

Generally, workers in the United States in H–2B status who extend their stay, change employers, or change the terms and conditions of employment will not be subject to the cap. Similarly, an H–2B worker who has previously been counted against the cap in the same fiscal year that the proposed employment begins, will not be subject to the cap if the employer names the worker on the petition and indicates that he/she has already been counted. A spouse and any children of H–2B workers classified as H–4 nonimmigrants are also not counted against this cap. Finally, H–2B petitions for two other categories of workers are exempt from the H–2B cap: Fish roe processors, fish roe technicians, and supervisors of fish roe processing, as well as workers performing labor or services in the Commonwealth of the Northern Mariana Islands or Guam from November 28, 2009, until December 31, 2019.

H–2B Temporary Labor Certification Process

The standards and procedures governing the submission and processing of H–2B labor certification applications are set forth in § 655.15 and §§ 655.30–655.35. These regulations generally require, among other things, that a registered employer with a non-emergency situation seeking an H–2B TLC file a completed H–2B application with the National Processing Center (NPC) designated by the OFLC Administrator. *See* 20 CFR 655.15. Except for employers that qualify for emergency procedures at § 655.17, employers that fail to register under the procedures in § 655.11 and/or that fail to submit a Prevailing Wage Determination (PWD) obtained under § 655.10 will not be eligible to file and their H–2B applications will be returned without review.

The Department's regulations require the employer, at the time of filing, to include a signed and dated appendix attesting to compliance with all regulatory assurances and obligations; a valid PWD; a copy of the job order submitted concurrently to the State Workforce Agency serving the area of intended employment; a copy of all contracts and agreements with foreign labor recruiters executed in connection with the job opportunities; and all other applicable documentation supporting the H–2B application. *See* 20 CFR 655.15(a). A completed H–2B application must be filed no more than 90 calendar days and no fewer than 75 calendar days before the employer's date of need (start date for the work). *See* 20 CFR 655.15(b).

The Department's regulations provide that H–2B applications and job orders filed with the NPC are reviewed by the Certifying Officer (CO) for compliance with all applicable program requirements. *See* 20 CFR 655.30(a). Employers have the option of filing H–2B applications electronically or by mail, and, according to procedures announced on June 1, 2018, the NPC sequentially assigns H–2B applications to NPC analysts based on the calendar receipt date and time measured to the millisecond and on Eastern Time, *e.g.,* 12:00:00.000 a.m. Once each H–2B application is assigned, NPC analysts initiate review of each application in the order of receipt date and time, and in accordance with all regulatory requirements.

Based on the NPC analyst's review, the CO authorizes issuance of either a Notice of Acceptance (NOA) under § 655.33 or a Notice of Deficiency (NOD) under § 655.31. Where there are deficiencies in the H–2B application or job order, the NOD provides the employer with 10 business days to correct the deficiencies or file an appeal with the Department's Office of Administrative Law Judges. Where necessary, the CO may authorize the issuance of a second NOD of the employer's H–2B application or job order in order to obtain regulatory compliance. NPC analysts process employer responses to NODs as

expeditiously as possible based upon the date responses are received and, if deemed compliant, the CO authorizes the issuance of a NOA. The NOA authorizes the next step in the process—the recruitment of U.S. workers—and specifies a date on which the employer must provide an initial written report of its recruitment efforts. The Department's regulations establish minimum recruitment activities that employers must conduct within 14 calendar days from the date the NOA was issued, unless otherwise instructed by OFLC. *See* 20 CFR 655.40–46. Employer-conducted recruitment typically occurs between 40 and 60 calendar days before the date of need and must be completed before the employer submits the recruitment report to the NPC for review meeting the content requirements under § 655.48.

Recruitment reports are reviewed and processed by NPC analysts based on the day they are received, irrespective of the date and time the employer's H–2B application was originally received. Upon review of the recruitment report, the CO may authorize the issuance of a full or partial TLC or deny the employer's H–2B application. OFLC grants a TLC only after the employer's H–2B application has met all the requirements for approving labor certification under § 655.50 and its subpart. In accordance with regulatory requirements, the NPC sends all certified H–2B applications to the employer, or the employer's authorized attorney or agent, by means normally assuring next-day delivery. To ensure a fair consideration of all employer applications, the NPC does not provide ''expedited processing'' services on employer requests for a TLC.

Although not required by the INA or regulation, OFLC strives to issue final determinations no later than 30 calendar days before the employer's start date for the work—a standard that is similar in nature to the H–2A program. Once OFLC grants a TLC, the employer is eligible to file a petition (Form I–129, *Petition for Nonimmigrant Worker*) with the appropriate United States Citizenship and Immigration Services (USCIS) service center for adjudication. *See* 8 CFR 214.2(h)(2)(i)(A).

History of Changes to H–2B Processing and Reasons for Updating Current Approach

Because of the intense competition for H–2B visas in recent years, the semi-annual visa allotment, and the regulatory requirement that employers apply with OFLC for temporary labor certification 75 to 90 calendar days before the date of need, employers who wish to obtain visas under the semi-annual allotment for periods of need beginning April 1 must promptly apply for a TLC and file a petition with USCIS before the 66,000 annual visa cap is reached. As a result, OFLC typically experiences significant ''spikes'' in H–2B applications for temporary or seasonal jobs that are expected to start during the United States' spring and summer months.

Prior to 2018, OFLC processed applications irrespective of the time of day the application was filed and processed applications based on the day they were filed. On January 1, 2018, OFLC received approximately 4,498 applications covering 81,008 worker positions for April 1 start dates of work, exceeding the semi-annual visa allotment by nearly 250 percent. This was the first time in recent years that applications received within the first day of the filing period exceeded the semi-annual visa allocation. In order to promote fairness in response to the unprecedented volume of applications, OFLC determined it was necessary to adjust its application processing procedures to better reflect the sequential order in which applications were filed. Thus, on January 17, 2018, OFLC announced that it would begin to release certified applications on February 20, 2018, in sequential order based on the day and time the applications were filed (January 17 procedures).

As participation in the H–2B program has grown significantly over the years, OFLC anticipated that it would continue to receive a significant surge of applications within a short timeframe during its next application cycle. In order to provide an equitable solution to this problem, on June 1, 2018, OFLC announced that it would sequentially assign H–2B applications to analysts based on the calendar date and time on which the applications were received, based on Eastern Time, and measured to the millisecond (*e.g.,* 12:00:00.000 a.m.) (June 1 procedures). Based on the June 1 procedures, once these applications were assigned to the analysts, the analysts would initiate review of applications in the order of receipt date and time, issue first actions on a rolling basis, and issue certifications as all regulatory requirements were met.

OFLC implemented the June 1 procedures after considering all available data as well as OFLC's experience in processing H–2B applications to date. However, as a result of stakeholder comments and the most recent filing period, OFLC has determined it is necessary to reassess those procedures. The June 1 procedures were in effect in January 2019, when OFLC received approximately 5,276 applications covering more than 96,400 worker positions for start dates of work on April 1, exceeding the semi-annual visa allotment by nearly 300 percent. Within the first five minutes of opening the semi-annual H–2B certification process on January 1, 2019, the Department's network infrastructure supporting OFLC's electronic filing system experienced more than 22,900 server login attempts, in contrast with only 721 attempts in approximately the same time period for the 2018 filing season. This unprecedented volume of simultaneous system users—30 times the number of users in the previous year—ultimately caused the electronic filing system to become unresponsive and prevented almost all employers from filing H–2B applications. Although the Department was able to restore OFLC's electronic filing system by January 7, 2019, some employers continued to report technical difficulties with accessing the electronic filing system.

OFLC previously concluded that the assignment of applications to NPC analysts based on date and time of receipt was the most equitable method of addressing the significant volume of H–2B applications received. However, it did not anticipate the burdens this approach would create on its electronic filing system, network infrastructure, and staff resources on January 1, 2019. Given the growing demand for H–2B visas, and related demand for TLCs, OFLC expects that the demands on OFLC's information technology infrastructure will continue to increase. In addition, OFLC has determined that the current approach does not account for technological issues that an individual user may experience on his/her end that could impact his/her ability to participate in the program. In addition, because the first filing date for each semi-annual cap period occurs on or near a Federal holiday when many businesses may be closed, OFLC is amending its procedures to provide increased flexibility to allow those employers an opportunity to participate in the program. For these reasons, OFLC has concluded that changes to the procedures under which H–2B applications are assigned to NPC analysts are necessary to promote a more orderly and fair process for all employers seeking access to the H–2B visa program. OFLC believes that the process described below balances employers' interest in utilizing the H–2B program with OFLC's interest in

ensuring that access to its filing system is equitable and occurs with no user disruption.

Random Selection Process for Assigning H–2B Applications

For employers seeking a TLC to employ H–2B workers beginning on or after October 1, 2019, OFLC plans to randomly establish the order in which all H–2B applications will be assigned to NPC analysts for review and processing in accordance with § 655.30. Based on its experience and feedback from stakeholders, the Department has determined that this process will be most effective in promoting a fair and orderly assignment of applications for OFLC review.

This assignment process will be dependent on when employers submit their applications and the start dates they request. OFLC will first process applications from employers seeking TLCs to employ H–2B workers beginning on the *earliest start date* of work permitted under the semi-annual allotments set forth at sections 214(g)(1)(B) and 214(g)(10) of the INA where those employers *submitted applications during the initial three calendar days* of the time period for filing for the relevant semi-annual visa allotment.

Once those applications have all received a NOA or NOD, OFLC will then begin to process applications from all other employers, including: (1) Employers seeking TLCs to employ H–2B workers *beginning on dates later than the earliest start date of work* permitted under the semi-annual allotments during the initial three-day filing window, and (2) employers seeking TLCs to employ H–2B workers beginning on the *earliest start date of work* permitted under the semi-annual visa allotments if their *applications are filed outside of the initial three-day filing window.*

Random Selection Process for Assigning H–2B Applications Received During the Initial Three Days of the Filing Period for the Earliest Start Date of Work

OFLC will randomly order for processing all of the completed H–2B applications requesting the earliest permissible start date of work and filed during the initial three calendar days of the time period for filing for the relevant semi-annual visa allotment. The rationale for using a three-day filing window is explained below. As an example, for employers seeking a TLC to employ H–2B nonimmigrant workers on April 1, 2020—which is the earliest start date of work permitted under the second semi-annual allotment of H–2B visas for Fiscal Year (FY) 2020—OFLC will randomly order for processing all of the completed H–2B applications that are received on January 2 through January 4 (the first three calendar days to file H–2B applications under § 655.15(b) in the second half of FY 2020 because 2020 is a leap year containing an additional day in February).

More specifically, on the next business day following this three-day filing window, using a standard computer-generated process for randomizing values in a data set, OFLC will generate and assign a unique random number to each completed H–2B application filed within the three-day filing window with the earliest start date of work. The applications will be sorted in ascending order based on the unique random number assigned to each application. Based on that randomly-generated order, OFLC will select the number of H–2B applications that, combined, contain a sufficient number of worker positions to reach the semiannual visa allotment under the INA (*i.e.,* 33,000). These applications will be placed in an H–2B ''Assignment Group'' (*i.e.,* Group A) and assigned to NPC analysts for processing in a manner consistent with §§ 655.30–33. The initial H–2B Assignment Group (*i.e.,* Group A) will always include the number of H–2B applications containing a sufficient amount of worker positions to reach the applicable numerical visa cap, even if the numerical limits of the INA are subsequently changed.

OFLC will then assign to additional Assignment Groups, in ascending sequential order, all remaining H–2B applications that were filed during the initial three-day filing window that requested the earliest start date of work permitted. Each H–2B Assignment Group after Group A (*e.g.,* Group B, Group C, *etc.*) will total no more than 20,000 worker positions, or roughly 1,000 applications per group.

OFLC will assign to NPC analysts all of the H–2B applications placed in Group A for issuance of NODs or NOAs. Once all applications in Group A are issued a NOD or NOA, OFLC will assign to NPC analysts all H–2B applications placed in Group B for issuance of NODs or NOAs. This process will be repeated until each group of H–2B applications is assigned to NPC analysts for processing and NODs or NOAs are issued.

That the number of applications in the initial Assignment Group (*i.e.,* Group A) is tied to the numerical cap is not meant to be determinative of which employers will ultimately receive H–2B visas, nor does it preclude employers whose applications are in subsequent groups from ultimately receiving H–2B visas. OFLC has simply determined that the statutory cap is a reasonable benchmark for this initial assignment and believes this—in addition to the notice provided, as explained below—will provide the public and interested stakeholders a more transparent view of the process.

If the H–2B applications received during the initial three-day period collectively request certification for fewer worker positions than the statutory numerical limitation, all H–2B applications filed within that time period and requesting workers for the earliest possible start date of work will randomly be given a unique number and placed into the same group for assignment to and processing by NPC analysts.

OFLC has chosen to utilize a three-day filing window at the outset of each application cycle for several reasons. First, the three-day filing window will alleviate the strain placed on OFLC's electronic filing system and network infrastructure that results from a surge of applications submitted at the same time. Second, the window will provide employers that file on the earliest possible date, which in most instances falls on a Federal holiday or the day before a Federal holiday, with a reasonable period of time to submit their H–2B applications or resolve any technological issues they might face during filing. Third, under the previous procedures, mailed applications were put at a distinct disadvantage. A three-day filing window allows applications filed by mail to be included in the random selection process, thus placing them on equal footing with employers who file electronically. Fourth, and as explained below, because applicants will be able to see which processing group they have been placed in, and the general number of applications in that processing group, these procedural changes may reduce some associated costs for employers who spend time and resources related to preparing applications, responding to NODs, and conducting advertising and recruitment for qualified U.S. workers without knowing whether their H–2B petitions will be accepted by USCIS due to the statutory semi-annual visa allotments.

Random Selection Process for Assigning All Other H–2B Applications

As noted above, for all other employers seeking a TLC to employ H–2B workers—including employers who are seeking a TLC to employ H–2B workers beginning on a date that is later than the earliest start date of work permitted under the semi-annual

allotments and employers seeking a TLC to employ H–2B workers beginning on the earliest start date of work permitted if their application is filed outside of the initial three-day filing window—OFLC will randomly assign for processing all of the completed H–2B applications filed on a single calendar day *after* it finishes processing NOAs and NODs for applications filed during the initial three-day filing window (as discussed above). As an example, for employers seeking a TLC to employ H–2B nonimmigrant workers on April 2, 2020—which is the next start date of work permitted under the second semi-annual allotment of H–2B visas for FY 2020— OFLC will randomly assign to NPC analysts for processing all of the completed H–2B applications that are filed on January 3 with an April 2, 2020 start date of work, after OFLC finishes processing NOAs and NODs for the applications filed during the initial three-day filing window for the earliest start day of work.

Application Processing After Random Selection and Assignment Occur

Once the random assignment process is completed, NPC analysts will review each H–2B application in accordance with § 655.30 and current standard operating procedures. Following issuance of NOAs and/or NODs in accordance with procedures outlined above, H–2B applications will be processed as each successive stage in the process is completed. Employers receiving NOAs may proceed to meet the additional regulatory requirements, including recruitment of U.S. workers and submission of recruitment reports. Employers receiving NODs must correct any deficiencies and receive NOAs before proceeding to meet the additional regulatory requirements.

Recruitment reports will be reviewed and processed based on the day they are received, and the CO will authorize the release of certified H–2B applications in accordance with standard operating procedures and where all the requirements for granting a TLC under the subpart are met as of that day. The CO will continue to process and authorize the issuance of final determinations on all H–2B applications that are received, irrespective of whether the employer is seeking to employ H–2B nonimmigrant workers in cap-exempt positions. Additionally, the CO will process and authorize the issuance of rejections, request for withdrawals, and denials of labor certification applications in accordance with standard operating procedures.

Public Notifications

OFLC intends to issue several public announcements as applications are received and processed under the procedures described above. Once the random assignment process is completed, as described above, OFLC will provide written notification to employers and, if applicable, employers' authorized representatives of their H–2B Assignment Group. Within five business days after the random assignment process is completed, OFLC will place on its website a listing of the H–2B applications assigned to each H–2B Assignment Group. Second, OFLC will provide the public with updates on its website related to the number and percentage of H–2B applications issued a first action within each H–2B Assignment Group. Finally, OFLC will provide regular updates on its website related to the number of H–2B applications certified with the same date of filing, including the number of worker positions, so the public is aware of the general timeframes in which the semi-annual visa allotment may be reached.

Because of the public's wide use of OFLC's website, the posting of information on the OFLC website provides a timelier and more efficient method of disseminating such information to the public than publication of the information in the **Federal Register**. The public frequently turns to OFLC's website for general information on labor certification requirements, regulations and forms, specific case status information, and processing times for H–2B applications. Therefore, all notifications regularly updating the public on implementing these procedures will be made available on or through the OFLC website at *www.foreignlaborcert.doleta.gov.*

Request for Comments and Effective Date

These new procedures will take effect on July 3, 2019. OFLC seeks comments on the above procedures. Comments may be sent to *H2BReform.Comments@dol.gov* or mailed to Thomas M. Dowd, Deputy Assistant Secretary, Employment and Training Administration, U.S. Department of Labor, Box PPII 12–200, 200 Constitution Avenue NW, Washington, DC 20210 until 30 days after issuance of this notice in the **Federal Register**. OFLC will review all of the comments received and will make any changes it determines are appropriate prior to July 3, 2019.

Molly E. Conway,

Acting Assistant Secretary for the Employment and Training, Labor.

[FR Doc. 2019–03809 Filed 3–1–19; 8:45 am]

BILLING CODE 4510–FP–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2019–015]

Change in Comment Process for Records Schedules

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: We are changing the process for public review of and comment on records schedules (Federal agency requests for records disposition authority) to rely on the Federal eRulemaking Portal, at *https://www.regulations.gov.*

DATES: This change will take place on March 4, 2019.

ADDRESSES: National Archives and Records Administration, Records Management Operations (ACR), Room 2200, 8601 Adelphi Road, College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Margaret Hawkins, Director, Records Management Operations, by mail at the address above, by phone at 301.837.1799, or by email at *request.schedule@nara.gov.* Please also contact us for information on submitting your comment by another means if you are unable to use *regulations.gov* or wish to include confidential information in a comment.

SUPPLEMENTARY INFORMATION: NARA publishes notices in the **Federal Register** for records schedules in which agencies propose to destroy records they no longer need to conduct agency business. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

Each year, Federal agencies create billions of records. To control this accumulation, agencies prepare schedules proposing periods for retaining and disposing of records. These schedules, when approved by NARA, provide for transfer into the National Archives of permanent, historically valuable records and authorize disposal of all other records after the agency no longer needs them to conduct its business.

Agencies may not destroy Federal records without the approval of the

Archivist of the United States. The Archivist grants this approval only after thoroughly considering the administrative use needs of the agency that originated the records, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public notice, review, and comment on proposed records schedules is part of the Archivist's consideration process.

Currently, we publish notice in the **Federal Register** of records schedules open for comment, but people who wish to review and comment on the schedules must request copies of the actual documents, submit comments, and receive responses via mail or email. The new process will allow people to review and comment on open records schedules and accompanying appraisal memoranda at the Federal eRulemaking Portal, *https://www.regulations.gov.* We will also post consolidated responses to comments at the same location.

Under the new process, we will post batches of records schedules to *regulations.gov* as ''other'' documents in the same docket as the notice. The schedules and related memoranda will remain open for comment for a period of 45 days. You will be able to comment on individual schedules at *regulations.gov* on or before the deadline stated in the notice. We will not accept late comments.

Comments you submit on *regulations.gov,* including any personal information and attachments, will be posted to the public docket unchanged. Because comments are public, commenters are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you should contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments received by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on *regulations.gov* a ''Consolidated Response'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Response, whether or not you submit a comment.

Copies of schedules and consolidated responses will remain on the *regulations.gov* website after the comment period has passed, although all commenting features will be disabled when the comment period ends.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* within two or three weeks after the Archivist approves them. The RCS contains all schedules approved since 1973.

This new process eliminates the need to request copies of the schedules and appraisal memoranda, as has been the process since 1985. You will also no longer need to email or send comments on proposed records schedules, but will instead be able to provide comments directly on *regulations.gov.* The comment period is also being extended from 30 days to 45 days.

We are making this change as a result of clear, widespread interest from the public in a web-based platform for a more modern, transparent, and efficient review and comment process. We are interested in receiving feedback on this new process and will continuously strive to improve the experience for public review of proposed records schedules. You may send feedback to us any time at *request.schedule@nara.gov.*

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2019–03826 Filed 3–1–19; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Astronomy and Astrophysics Advisory Committee; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Astronomy and Astrophysics Advisory Committee (#13883) (Teleconference).

Date and Time: March 28, 2019; 12:00 p.m.–3:00 p.m. EDT.

Place: National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314 (Teleconference).

Type of Meeting: Open.

Attendance information for the meeting will be forthcoming on the website: *https://www.nsf.gov/mps/ast/aaac.jsp.*

Contact Person: Dr. Christopher Davis, Program Director, Division of Astronomical Sciences, Suite W 9136, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone: 703–292–4910.

Purpose of Meeting: To provide advice and recommendations to the National Science Foundation (NSF), the National Aeronautics and Space Administration (NASA) and the U.S. Department of Energy (DOE) on issues within the field of astronomy and astrophysics that are of mutual interest and concern to the agencies.

Agenda: To provide updates on Agency activities and to discuss the Committee's draft annual report.

Dated: February 26, 2019.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2019–03719 Filed 3–1–19; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; Presidential Awards for Excellence in Mathematics and Science Teaching (PAEMST), State Coordinator (SC) Survey

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by May 3, 2019 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite W18200, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: Presidential Awards for Excellence in Mathematics

and Science Teaching (PAEMST), State Coordinator (SC) Survey.

OMB Number: 3145–0241.

Expiration Date of Approval: September 30, 2019.

Type of Request: Renewal.

Abstract: The PAEMST is a White House program established by Congress in 1983 authorizing the President to bestow up to 108 awards each year to teachers of mathematics and science at the elementary and secondary levels. The NSF is the designated federal agency for administration of this Presidential program. Awards are given to mathematics and science (including computer science) teachers from each of the 50 states and four U.S. jurisdictions. The jurisdictions are Washington DC; Puerto Rico; Department of Defense Education Activity schools; and the U.S. territories as a group (American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the U.S. Virgin Islands). The award recognizes those teachers who develop and implement a high-quality instructional program that is informed by content knowledge and enhances student learning. Since the program's inception, more than 4,300 teachers have been recognized for their contributions in the classroom and to their profession. Awardees serve as models for their colleagues, inspiration to their communities, and leaders in the improvement of mathematics and science (including computer science) education.

The State Coordinator (SC) manages the PAEMST program within his or her state or jurisdiction. SCs recruit eligible nominees, select and assign mentors to nominees, coordinate the selection committee, and plan local recognition events within their State. They also carry out the responsibilities as noted in the ''Operational Handbook for State-Level Science and Mathematics Coordinators.''

The purpose of this survey is to seek feedback from the 120 SCs regarding PAEMST management within their state or jurisdiction. The NSF, PAEMST support team will ask directed questions using the survey to gather information that may specifically address the methods and recruitment efforts that SCs use to support the attracting of prospective award nominees. Additional survey areas may also include:

- Applicant Mentoring
- Mentor Training
- State selection Committee
- State selection Process
- Applicant and State Finalist Notification and Recognition
- In-kind contributions

The survey will evaluate the impact SCs have on attracting prospective award nominees to PAEMST. This will be conducted as a web-based survey.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 30–40 minutes for State Coordinators.

Respondents: Individuals.

Estimated Number of Responses per Form: 120 Coordinators.

Estimated Total Annual Burden on Respondents: 80 hours. (120 Coordinators at 40 minutes per survey = 80 hours).

Frequency of Response: One per application cycle.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the PAEMST functions, including whether the information shall have practical utility; (b) the accuracy of the NSF's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Dated: February 26, 2019.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2019–03749 Filed 3–1–19; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; Grantee Reporting Requirements for Materials Research Science and Engineering Centers (MRSECs)

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by May 3, 2019 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite W18200, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: Grantee Reporting Requirements for Materials Research Science and Engineering Centers (MRSECs).

OMB Number: 3145–0230.

Expiration Date of Approval: September 30, 2019.

Type of Request: Intent to seek approval to renew an information collection.

Overview of This Information Collection

The Materials Research Science and Engineering Centers (MRSECs) Program supports innovation in interdisciplinary research, education, and knowledge transfer. MRSECs build intellectual and physical infrastructure within and between disciplines, weaving together knowledge creation, knowledge integration, and knowledge transfer. MRSECs conduct world-class research through partnerships of academic institutions, national laboratories, industrial organizations, and/or other public/private entities. New knowledge thus created is meaningfully linked to society.

MRSECs enable and foster excellent education, integrate research and education, and create bonds between learning and inquiry so that discovery and creativity more fully support the learning process. MRSECs capitalize on diversity through participation in center activities and demonstrate leadership in the involvement of groups underrepresented in science and engineering.

MRSECs are required to submit annual reports on progress and plans, which are used as a basis for performance review and determining the level of continued funding. To support this review and the management of a Center, MRSECs will be required to develop a set of

management and performance indicators for submission annually to NSF via the Research Performance Project Reporting module in *Research.gov* and an external technical assistance contractor that collects programmatic data electronically. These indicators are both quantitative and descriptive and may include, for example, the characteristics of center personnel and students; sources of financial support and in-kind support; expenditures by operational component; characteristics of industrial and/or other sector participation; research activities; education activities; knowledge transfer activities; patents, licenses; publications; degrees granted to students involved in Center activities; descriptions of significant advances and other outcomes of the MRSEC effort. Such reporting requirements are included in the cooperative agreement that is binding between the academic institution and NSF.

Each Center's annual report will address the following categories of activities: (1) Research, (2) education, (3) knowledge transfer, (4) partnerships, (5) shared experimental facilities, (6) diversity, (7) management, and (8) budget issues.

For each of the categories the report will describe overall objectives for the year, problems the Center has encountered in making progress towards goals, anticipated problems in the following year, and specific outputs and outcomes.

MRSECs are required to file a final report through the RPPR and external technical assistance contractor. Final reports contain similar information and metrics as annual reports, effectively they constitute the last annual report; the Program Officer maintains a cumulative database with all relevant achievements and metrics.

Use of the Information: NSF will use the information to continue funding of the Centers, and to evaluate the progress of the program.

Estimate of Burden: 80 hours per center for 20 centers for a total of 1,600 hours.

Respondents: Non-profit institutions.

Estimated Number of Responses per Report: One from each of the 20 MRSECs.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: February 26, 2019.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2019–03750 Filed 3–1–19; 8:45 am]

BILLING CODE 7555–01–P

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Occupational Safety and Health Review Commission (OSHRC) is revising the notice for Privacy Act system-of-records OSHRC–4.

DATES: Comments must be received by OSHRC on or before April 3, 2019. The revised system of records will become effective on that date, without any further notice in the **Federal Register**, unless comments or government approval procedures necessitate otherwise.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: rbailey@oshrc.gov.* Include ''PRIVACY ACT SYSTEM OF RECORDS'' in the subject line of the message.
- *Fax:* (202) 606–5417.
- *Mail:* One Lafayette Centre, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457.
- *Hand Delivery/Courier:* Same as mailing address.

Instructions: All submissions must include your name, return address, and email address, if applicable. Please clearly label submissions as ''PRIVACY ACT SYSTEM OF RECORDS.''

FOR FURTHER INFORMATION CONTACT: Ron Bailey, Attorney-Advisor, Office of the General Counsel, via telephone at (202) 606–5410, or via email at *rbailey@oshrc.gov*.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, 5 U.S.C. 552a(e)(4), requires federal agencies such as OSHRC to publish in the **Federal Register** notice of any new or modified system of records. OSHRC published a modified system-of-records notice for OSHRC–4 on November 13, 2018, 83 FR 56380. In response to a comment received from the U.S. Equal Employment Opportunity Commission (EEOC), OSHRC is revising the opening paragraph to its routine uses to specify that disclosure of medical and/or genetic information pursuant to these uses is limited by Section 501 of the Rehabilitation Act of 1973 and Title II of the Genetic Information Nondiscrimination Act (GINA) of 2008. These statutes and the regulations implementing them, as set forth in 29 CFR pt. 1630 (Rehabilitation Act) and 29 CFR pt. 1635 (GINA), specify the circumstances under which federal agencies may disclose protected medical and/or genetic information. Pointing to Routine Uses 3 and 4 as examples, the EEOC commented that, as currently drafted, the system-of-records notice ''would permit disclosure of protected medical and/or genetic information in system records in circumstances beyond what the Rehabilitation Act and GINA permit.'' As detailed below, OSHRC is revising the opening paragraph to its routine uses to limit disclosure of such information in accordance with these statutory and regulatory requirements.

The revised routine use section of OSHRC–4 is provided below.

SYSTEM NAME AND NUMBER

Payroll and Related Records, OSHRC–4.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

(1) Paper and electronic files are maintained by the Office of the Executive Director, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457; (2) pursuant to an interagency agreement, payroll records are stored electronically by the U.S. Department of Agriculture, National Finance Center (NFC), P.O. Box 60000, New Orleans, LA 70160–0001.

SYSTEM MANAGER(S):

Human Resources Specialist, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457; (202) 606–5100.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information

contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected, and to the extent disclosure of any medical and/or genetic information is in compliance with Section 501 of the Rehabilitation Act of 1973 and Title II of the Genetic Information Nondiscrimination Act (GINA) of 2008. With respect to medical and genetic information protected under the Rehabilitation Act and/or GINA, records will be withheld or redacted to comply with the specific confidentiality and disclosure requirements set forth by the U.S. Equal Employment Opportunity Commission at 29 CFR pt. 1630 (Rehabilitation Act) and 29 CFR pt. 1635 (GINA). With these limitations, records may be disclosed as a routine use:

(1) To the Department of Justice (DOJ), or to a court or adjudicative body before which OSHRC is authorized to appear, when any of the following entities or individuals—(a) OSHRC, or any of its components; (b) any employee of OSHRC in his or her official capacity; (c) any employee of OSHRC in his or her individual capacity where DOJ (or OSHRC where it is authorized to do so) has agreed to represent the employee; or (d) the United States, where OSHRC determines that litigation is likely to affect OSHRC or any of its components—is a party to litigation or has an interest in such litigation, and OSHRC determines that the use of such records by DOJ, or by a court or other tribunal, or another party before such tribunal, is relevant and necessary to the litigation.

(2) To an appropriate agency, whether federal, state, local, or foreign, charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes civil, criminal or regulatory violations, and such disclosure is proper and consistent with the official duties of the person making the disclosure.

(3) To a federal, state, or local agency maintaining civil, criminal or other relevant enforcement information, such as current licenses, if necessary to obtain information relevant to an OSHRC decision concerning the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit.

(4) To a federal, state, or local agency, in response to that agency's request for a record, and only to the extent that the information is relevant and necessary to the requesting agency's decision in the matter, if the record is sought in connection with the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit by the requesting agency.

(5) To an authorized appeal grievance examiner, formal complaints manager, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee, only to the extent that the information is relevant and necessary to the case or matter.

(6) To OPM in accordance with the agency's responsibilities for evaluation and oversight of federal personnel management.

(7) To officers and employees of a federal agency for the purpose of conducting an audit, but only to the extent that the record is relevant and necessary to this purpose.

(8) To OMB in connection with the review of private relief legislation at any stage of the legislative coordination and clearance process, as set forth in Circular No. A–19.

(9) To a Member of Congress or to a person on his or her staff acting on the Member's behalf when a written request is made on behalf and at the behest of the individual who is the subject of the record.

(10) To the National Archives and Records Administration (NARA) for records management inspections and such other purposes conducted under the authority of 44 U.S.C. 2904 and 2906.

(11) To appropriate agencies, entities, and persons when: (a) OSHRC suspects or has confirmed that there has been a breach of the system of records; (b) OSHRC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, OSHRC, the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OSHRC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(12) To NARA, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with FOIA, and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

(13) To another federal agency or federal entity, when OSHRC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(14) To the Internal Revenue Service (IRS) for investigation, and to private attorneys, pursuant to a power of attorney.

(15) To the IRS, a copy of an employee's Department of the Treasury Form W–2, Wage and Tax Statement.

(16) To state, city, or other local jurisdictions which are authorized to tax the employee's compensation, a copy of an employee's Form W–2. The record will be provided in accordance with a withholding agreement between the state, city, or other local jurisdiction and the Department of the Treasury pursuant to 5 U.S.C. 5516, 5517, and 5520, or in response to a written request from an appropriate official of the taxing jurisdiction. The request must include a copy of the applicable statute or ordinance authorizing the taxation of compensation and should indicate whether the authority of the jurisdiction to tax the employee is based on place of residence, place of employment, or both.

(17) To a city, copies of executed city tax withholding certifications, pursuant to a withholding agreement between the city and the Department of the Treasury (5 U.S.C. 5520), and in response to written requests from an appropriate city official to OSHRC's Office of the Executive Director.

(18) To NFC to effect issuance of paychecks via electronic fund transfers (EFT) to employees, and distribution of allotments and deductions to financial and other institutions, and for other authorized purposes.

(19) To the Federal Retirement Thrift Investment Board to update Section 401K type records and benefits; to the Social Security Administration to establish social security records and

benefits; to the Department of Labor, Office of Worker's Compensation to process compensation claims; to the Department of Defense to adjust military retirement; to health insurance carriers to process insurance claims; and to the Department of Veterans Affairs for the purpose of evaluating veteran's benefits to which the individual may be entitled.

(20) To other federal agencies to effect salary or administrative offsets, or for other purposes connected with the collection of debts owed to the United States, pursuant to sections 5 and 10 of the Debt Collection Act of 1982, as amended by the Debt Collection Improvement Act of 1996.

(21) To other federal, state, local or foreign agencies conducting computer matching programs to help eliminate fraud and abuse and to detect unauthorized overpayments made to individuals. When disclosures are made as part of computer matching programs, OSHRC will comply with the Computer Matching and Privacy Protection Act of 1988, and the Computer Matching and Privacy Protections Amendments of 1990.

(22) To the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services, the names, social security numbers, home addresses, dates of birth, dates of hire, quarterly earnings, employer identifying information, and state of hire of employees for the purpose of locating individuals to establish paternity, identifying sources of income, and for other child support enforcement actions as required by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, 42 U.S.C. 653(n).

(23) To ''consumer reporting agencies'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)) in accordance with 31 U.S.C. 3711(f).

HISTORY:

April 14, 2006, 71 FR 19556; August 4, 2008, 73 FR 45256; October 5, 2015, 80 FR 60182; September 28, 2017, 82 FR 45324; November 13, 2018, 83 FR 56380.

Dated: February 25, 2019.

Nadine N. Mancini,

General Counsel, Senior Agency Official for Privacy.

[FR Doc. 2019–03836 Filed 3–1–19; 8:45 am]

BILLING CODE 7600–01–P

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Occupational Safety and Health Review Commission (OSHRC) is revising the notice for Privacy Act system-of-records OSHRC–9 and renumbering it as OSHRC–2.

DATES: Comments must be received by OSHRC on or before April 3, 2019. The revised system of records will become effective on that date, without any further notice in the **Federal Register**, unless comments or government approval procedures necessitate otherwise.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: rbailey@oshrc.gov.* Include ''PRIVACY ACT SYSTEM OF RECORDS'' in the subject line of the message.
- *Fax:* (202) 606–5417.
- *Mail:* One Lafayette Centre, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457.
- *Hand Delivery/Courier:* Same as mailing address.

Instructions: All submissions must include your name, return address, and email address, if applicable. Please clearly label submissions as ''PRIVACY ACT SYSTEM OF RECORDS.''

FOR FURTHER INFORMATION CONTACT: Ron Bailey, Attorney-Advisor, Office of the General Counsel, via telephone at (202) 606–5410, or via email at *rbailey@oshrc.gov.*

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, 5 U.S.C. 552a(e)(4), requires federal agencies such as OSHRC to publish in the **Federal Register** notice of any new or modified system of records. As detailed below, OSHRC is revising Visitors' Log Records, OSHRC–9, to account for changes in the names of the pertinent office and positions within the agency, and to update the reference to the applicable General Records Schedule for disposal of records. In addition, OSHRC has previously relied on blanket routine uses to describe the circumstances under which records may be disclosed. Going forward, as revised notices are published for new and modified systems of records, a full description of the routine uses—rather than a reference to blanket routine uses—will be included in each notice. This is simply a change in format that has not resulted in any substantive changes to the routine uses for this system of records. Finally, due to a previous rescission of a system-of-records notice, OSHRC–2 currently has no system of records assigned to it. OSHRC–9 is thus being renumbered as OSHRC–2.

The notice for OSHRC–2, provided below in its entirety, is as follows.

SYSTEM NAME AND NUMBER

Visitors' Log Records, OSHRC–2.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of the Executive Director, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457.

SYSTEM MANAGER(S):

Administrative Support Assistant, Office of the Executive Director, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457; (202) 606–5100.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Federal Property and Administrative Services Act of 1949, 40 U.S.C. 121(c).

PURPOSE(S) OF THE SYSTEM:

This system of records assists OSHRC in identifying each person who visits OSHRC's National office, and in restricting access based on his or her purpose for visiting that office.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records covers all individuals entering OSHRC National office who lack the proper credentials to enter without notifying OSHRC personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records includes the name of the visitor, the date of the visit, the company represented by the visitor, the arrival and departure times, the purpose of the visit, and the identity of the OSHRC escort.

RECORD SOURCE CATEGORIES:

Information in this system of records comes from the individual to whom the record pertains.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the

circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected:

(1) To the Department of Justice (DOJ), or to a court or adjudicative body before which OSHRC is authorized to appear, when any of the following entities or individuals—(a) OSHRC, or any of its components; (b) any employee of OSHRC in his or her official capacity; (c) any employee of OSHRC in his or her individual capacity where DOJ (or OSHRC where it is authorized to do so) has agreed to represent the employee; or (d) the United States, where OSHRC determines that litigation is likely to affect OSHRC or any of its components—is a party to litigation or has an interest in such litigation, and OSHRC determines that the use of such records by DOJ, or by a court or other tribunal, or another party before such tribunal, is relevant and necessary to the litigation.

(2) To an appropriate agency, whether federal, state, local, or foreign, charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes civil, criminal or regulatory violations, and such disclosure is proper and consistent with the official duties of the person making the disclosure.

(3) To a federal, state, or local agency maintaining civil, criminal or other relevant enforcement information, such as current licenses, if necessary to obtain information relevant to an OSHRC decision concerning the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit.

(4) To a federal, state, or local agency, in response to that agency's request for a record, and only to the extent that the information is relevant and necessary to the requesting agency's decision in the matter, if the record is sought in connection with the hiring, appointment, or retention of an employee; the issuance, renewal, suspension, or revocation of a security clearance; the execution of a security or suitability investigation; the letting of a contract; or the issuance of a license, grant or other benefit by the requesting agency.

(5) To an authorized appeal grievance examiner, formal complaints manager, equal employment opportunity investigator, arbitrator, or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee, only to the extent that the information is relevant and necessary to the case or matter.

(6) To OPM in accordance with the agency's responsibilities for evaluation and oversight of federal personnel management.

(7) To officers and employees of a federal agency for the purpose of conducting an audit, but only to the extent that the record is relevant and necessary to this purpose.

(8) To OMB in connection with the review of private relief legislation at any stage of the legislative coordination and clearance process, as set forth in Circular No. A–19.

(9) To a Member of Congress or to a person on his or her staff acting on the Member's behalf when a written request is made on behalf and at the behest of the individual who is the subject of the record.

(10) To the National Archives and Records Administration (NARA) for records management inspections and such other purposes conducted under the authority of 44 U.S.C. 2904 and 2906.

(11) To appropriate agencies, entities, and persons when: (a) OSHRC suspects or has confirmed that there has been a breach of the system of records; (b) OSHRC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, OSHRC, the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with OSHRC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(12) To NARA, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with FOIA, and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

(13) To another federal agency or federal entity, when OSHRC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored on paper in binders.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records can be retrieved manually by name or date.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained and disposed of in accordance with NARA's General Records Schedule 5.6, Item 111.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are maintained in a binder placed on the front desk. During duty hours, the binder is under surveillance of personnel occupying the front desk. After duty hours, the front desk can be accessed only by those who possess an office key or access card.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.6 (procedures for requesting records).

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457. For an explanation on the specific procedures for contesting the contents of a record, refer to 29 CFR 2400.8 (Procedures for requesting amendment), and 29 CFR 2400.9 (Procedures for appealing).

NOTIFICATION PROCEDURES:

Individuals interested in inquiring about their records should notify: Privacy Officer, OSHRC, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457. For an explanation on how such requests should be drafted, refer to 29 CFR 2400.5 (notification), and 29 CFR 2400.6 (procedures for requesting records).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

April 14, 2006, 71 FR 19556; August 4, 2008, 73 FR 45256; October 5, 2015, 80 FR 60182; and September 28, 2017, 82 FR 45324.

Dated: February 25, 2019.

Nadine N. Mancini,

General Counsel, Senior Agency Official for Privacy.

[FR Doc. 2019–03831 Filed 3–1–19; 8:45 am]

BILLING CODE 7600–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85203]

Order Granting Applications by Nasdaq BX, Inc. and Nasdaq PHLX LLC for Exemption Pursuant to Section 36(a) of the Exchange Act From the Rule Filing Requirements of Section 19(b) of the Exchange Act With Respect to Certain Order Audit Trail System Rules Incorporated by Reference

February 26, 2019.

Nasdaq BX, Inc. (''BX'') and Nasdaq PHLX LLC (''Phlx'') (each the ''Exchange'' and collectively, the ''Exchanges'') have filed with the Securities and Exchange Commission (''Commission'') an application for an exemption from the rule filing requirements of Section 19(b) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] with respect to certain rules of Financial Industry Regulatory Authority (''FINRA'') that the Exchanges seek to incorporate by reference. Section 36(a)(1) of the Exchange Act,[2] subject to certain limitations, authorizes the Commission to conditionally or unconditionally exempt any person, security, or transaction, or any class thereof, from any provision of the Exchange Act or rule thereunder, if necessary or appropriate in the public interest and consistent with the protection of investors.

The Exchanges each filed a proposed rule change [3] under Section 19(b) of the Exchange Act to amend their respective Order Audit Trail System (''OATS'') rules, some of which incorporate by reference the rules contained in the FINRA Rule 7400 Series entitled ''Order Audit Trail System,'' as such rules may be in effect from time to time, and reference FINRA Rule 4590 entitled ''Synchronization of Member Business Clocks.'' In the proposed rule changes, the Exchanges proposed to incorporate by reference FINRA Rules 4590, 7440, and 7450, and thus make these rules applicable to Exchange members in the case of BX, and member organizations in the case of Phlx.[4]

The Exchanges request, pursuant to Rule 0–12 under the Exchange Act,[5] that the Commission grant the Exchanges an exemption from the rule filing requirements of Section 19(b) of the Exchange Act for changes to each Exchange's rules that are effected solely by virtue of a change to FINRA Rules 4590, 7440, and 7450 that are incorporated by reference. Specifically, the Exchanges request that they be permitted to incorporate by reference changes made to FINRA Rules 4590, 7440, and 7450 that are cross-referenced in the Exchanges' rules without the need for each Exchange to separately file, pursuant to Section 19(b) of the Exchange Act, the same proposed rule change as filed by FINRA.[6]

The Exchanges represent that FINRA Rules 4590, 7440, and 7450 are regulatory in nature and that they do not intend to incorporate by reference any trading rules.[7] Further, the Exchanges represent that they will, as a condition of this exemption, provide written notice to their members whenever FINRA proposes a change to FINRA Rules 4590, 7440, and 7450.[8] Such notice will alert the members of each Exchange to the proposed rule change and give them an opportunity to comment on the proposal. The Exchanges state that they will also inform members in writing when the Commission approves any such proposed rule change.[9]

The Exchanges believe this exemption is appropriate because it will result in the Exchanges' rules pertaining to OATS compliance remaining consistent at all times, thus ensuring consistent regulation of joint members of the Exchanges, as well as the Nasdaq Market.[10]

The Commission has issued exemptions similar to the Exchanges' request.[11] In granting one such exemption in 2010, the Commission repeated a prior, 2004 Commission statement that it would consider similar future exemption requests from other self-regulatory organizations (''SROs''), provided that:

- An SRO wishing to incorporate rules of another SRO by reference has submitted a written request for an order exempting it from the requirement in Section 19(b) of the Exchange Act to file proposed rule changes relating to the rules incorporated by reference, has identified the applicable originating SRO(s), together with the rules it wants to incorporate by reference, and otherwise has complied with the procedural requirements set forth in the Commission's release governing procedures for requesting exemptive orders pursuant to Rule 0–12 under the Exchange Act; [12]
- The incorporating SRO has requested incorporation of categories of rules (rather than individual rules within a category) that are not trading rules (*e.g.,* the SRO has requested incorporation of rules such as margin, suitability, or arbitration); and
- The incorporating SRO has reasonable procedures in place to provide written notice to its members each time a change is proposed to the incorporated rules of another SRO.[13]

The Commission believes that the Exchanges have satisfied each of these

[1] 15 U.S.C. 78s(b).

[2] 15 U.S.C. 78mm(a)(1).

[3] *See* Securities Exchange Act Release Nos. 84227 (September 20, 2018), 83 FR 48483 (September 25, 2018) (SR–BX–2018–045) and 84545 (November 6, 2018), 83 FR 56387 (November 13, 2018) (SR–Phlx–2018–68).

[4] The Exchanges stated in their proposed rule changes specified in note 3 above that the changes would not be operative until such time as the Commission granted their request for an exemption from the rule filing requirements of Section 19(b) of the Exchange Act.

[5] 17 CFR 240.0–12.

[6] *See* Letter from T. Sean Bennett, Principal Associate General Counsel, Nasdaq Inc., to Brent J. Fields, Secretary, Commission, dated November 29, 2018.

[7] *See id.* at 2.

[8] The Exchanges also state that they will provide such notice on their websites in the same section they use to post their own proposed rule changes pursuant to Rule 19b–4(l) of the Exchange Act. In addition, the Exchanges state that their websites will include a link to the FINRA website where the proposed rule change would be located. *Id.*

[9] *Id.*

[10] *Id.*

[11] *See, e.g.,* Securities Exchange Act Release Nos. 80338 (March 29, 2017), 82 FR 16464 (April 4, 2017) (order granting exemptive request from MIAX PEARL, LLC relating to rules of Miami International Securities Exchange, LLC incorporated by reference); 72650 (July 22, 2014), 79 FR 44075 (July 29, 2014) (order granting exemptive requests from NASDAQ OMX BX, Inc. and the NASDAQ Stock Market LLC relating to rules of NASDAQ OMX PHLX LLC incorporated by reference); 67256 (June 26, 2012), 77 FR 39277, 39286 (July 2, 2012) (order approving SR–BX–2012–030 and granting exemptive request relating to rules incorporated by reference by the BX Options rules); 61534 (February 18, 2010), 75 FR 8760 (February 25, 2010) (order granting BATS Exchange, Inc.'s exemptive request relating to rules incorporated by reference by the BATS Exchange Options Market rules) (''BATS Options Market Order''); and 57478 (March 12, 2008), 73 FR 14521, 14539–40 (March 18, 2008) (order approving SR–NASDAQ–2007–004 and SR–NASDAQ–2007–080, and granting exemptive request relating to rules incorporated by reference by The NASDAQ Options Market).

[12] *See* 17 CFR 240.0–12 and Securities Exchange Act Release No. 39624 (February 5, 1998), 63 FR 8101 (February 18, 1998) (''Commission Procedures for Filing Applications for Orders for Exemptive Relief Pursuant to Section 36 of the Exchange Act; Final Rule'').

[13] *See* BATS Options Market Order, *supra* note 11 (citing Securities Exchange Act Release No. 49260 (February 17, 2004), 69 FR 8500 (February 24, 2004) (order granting exemptive request relating to rules incorporated by reference by several SROs) (''2004 Order'')).

conditions. Further, the Commission also believes that granting the Exchanges an exemption from the rule filing requirements under Section 19(b) of the Exchange Act will promote efficient use of the Commission's and the Exchanges' resources by avoiding duplicative rule filings based on simultaneous changes to identical rule text sought by more than one SRO.[14] The Commission therefore finds it appropriate in the public interest and consistent with the protection of investors to exempt the Exchanges from the rule filing requirements under Section 19(b) of the Exchange Act with respect to the above-described rules they incorporate by reference. This exemption is conditioned upon the Exchanges promptly providing written notice to their members whenever FINRA changes a rule that the Exchanges have incorporated by reference.

Accordingly, *it is ordered,* pursuant to Section 36 of the Exchange Act,[15] that the Exchanges are exempt from the rule filing requirements of Section 19(b) of the Exchange Act solely with respect to changes to the rules identified in their request that incorporate by reference certain FINRA rules that are the result of changes to such FINRA rules, provided that the Exchanges promptly provide written notice to their members whenever FINRA proposes to change a rule that the Exchanges have incorporated by reference.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–03736 Filed 3–1–19; 8:45 am]

BILLING CODE 8011–01–P

[14] *See* BATS Options Market Order, *supra* note 11, 75 FR at 8761; *see also* 2004 Order, *supra* note 13, 69 FR at 8502.

[15] 15 U.S.C. 78mm.

[16] 17 CFR 200.30–3(a)(76).

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

AGENCY: Small Business Administration.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before May 3, 2019.

ADDRESSES: Send all comments to Daniel Upham, Chief, Microenterprise Development Division, Office of Capital Access, Small Business Administration, 409 Third Street SW, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Daniel Upham, Chief, Microenterprise Development Division, Office of Capital Access, *Daniel.upham@sba.gov,* 202–205–7001, or Curtis B. Rich, Management Analyst, 202–205–7030, *curtis.rich@sba.gov.*

SUPPLEMENTARY INFORMATION: Section 853(c) of the National Defense Authorization Act for Fiscal Year 2019 (NDAA 2019), Public Law 115–232 (8/13/2018) requires the SBA to study the level of participation by intermediaries that are eligible to participate in the Agency's Microloan Program. To that end SBA plans to conduct a survey of this group of intermediaries to determine the reasons why some of them do not participate in the program. The survey will explore ways to encourage increased participation in the microloan program, and also decrease the costs associated with participation. Generally, the survey will look at the operations of the intermediaries, including structure, size, area of operations, and the nature of the services that they provide.

Intermediaries that are eligible for the program but do not currently participate will be asked to identify some of the factors that contribute to their non-participation in the program. The survey will also explore what factors could make the program more appealing to intermediaries and lead them to participate. The complete list of questions is available upon request from SBA.

Finally, as required by the NDAA 2019, the results of the study will be reported to the Committee on Small Business and Entrepreneurship of the Senate, and the Committee on Small Business of the House of Representatives.

Solicitation of Public Comments

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the requested information.

Summary of Information Collection

Title: SBA Study of Microenterprise Participation.

Form Number: N/A.

Description of Respondents: Organizations eligible to participate in the SBA Microloan Program.

Estimated Number of Respondents: 500.

Total Estimated Responses: 500.

Total Estimated Annual Hour Burden: 160 hours.

Curtis Rich,

Management Analyst.

[FR Doc. 2019–03720 Filed 3–1–19; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 10686]

Bureau of Political-Military Affairs; Rescission of Statutory Debarment of Rocky Mountain Instrument Company Under the International Traffic in Arms Regulations

SUMMARY: Notice is hereby given that the Department of State has rescinded the statutory debarment of Rocky Mountain Instrument Company included in **Federal Register** notice of September 8, 2010.

DATES: Rescission as of March 4, 2019.

FOR FURTHER INFORMATION CONTACT: Jae Shin, Director, Office of Defense Trade Controls Compliance, Bureau of Political-Military Affairs, Department of State (202) 632–2107.

SUPPLEMENTARY INFORMATION: Section 38(g)(4) of the Arms Export Control Act (AECA), 22 U.S.C. 2778(g)(4), prohibits the issuance of licenses or other approvals for the export of defense articles or defense services where the applicant, or any party to the export, has been convicted of violating the AECA and certain other U.S. criminal statues enumerated in § 38(g)(1) of the AECA. In addition, § 127.7(b) of the International Traffic in Arms Regulations (ITAR) provides for the statutory debarment of any person who has been convicted of violating or conspiring to violate the AECA. As stated in this provision, it is the policy of the Department of State not to consider applications for licenses or requests for approvals involving any person who has been statutorily debarred. Persons subject to statutory

debarment are prohibited from participating directly or indirectly in any activities that are subject to the ITAR.

In June 2010, Rocky Mountain Instrument Company (''RMI'') pleaded guilty to violating the AECA. On September 8, 2010, the Department notified the public of a statutory debarment imposed on RMI pursuant to ITAR § 127.7(c) related to RMI's criminal conviction via notice in the **Federal Register** (75 FR 54692). The notice provided that RMI was ''prohibited from participating directly or indirectly in the export of defense articles, including technical data, or in the furnishing of defense services for which a license or other approval is required.'' On May 9, 2016, the Department modified this statutory debarment to allow specific exceptions to the debarment of RMI without the submission of a transaction exception request as an element of the application, available to persons other than RMI but excluding persons acting for or on behalf of RMI in contravention of ITAR § 127.1(d).

In accordance with ITAR § 127.7(b) of the ITAR, reinstatement may only be approved after submission of a request by the debarred party. In response to such a request from RMI for reinstatement, the Department has conducted a thorough review of the circumstances surrounding the conviction, and has determined that RMI has taken appropriate steps to address the causes of the violations to warrant rescission of the notice of statutory debarment of RMI. Therefore, pursuant to ITAR § 127.7(b) the Department determines it is no longer in the national security and foreign policy interests of the United States to maintain the policy as applied to RMI, and the Department hereby rescinds the notice of RMI's statutory debarment.

The Department notes that the **Federal Register** notice of debarment for RMI stated that ''export privileges may be reinstated only at the request of the debarred person followed by the necessary interagency consultations, after a thorough review of the circumstances surrounding the conviction, and a finding that appropriate steps have been taken to mitigate any law enforcement concerns, as required by Section 38(g)(4) of the AECA. Unless export privileges are reinstated, however, the person remains debarred.'' (75 FR 54693). The Department is no longer requiring that export privileges be reinstated pursuant to ITAR § 127.11 and § 38(g)(4) of the AECA prior to the rescission of statutory debarment. This change in policy recognizes that the circumstances warranting statutory debarment may be different than those warranting the revocation of export privileges. The Department may find, as it does in this instance, that the national security and foreign policy interests of the United States are not advanced by maintaining the Department-imposed ITAR § 127.7(b) prohibition on persons convicted of violating or conspiring to violate the AECA from ''participating directly or indirectly in any activities that are subject to [the ITAR]'' and where the debarred person may not meet the requirements of ITAR § 127.11(b) (implementing the restrictions of § 38(g)(4) of the AECA).

This notice rescinds the statutory debarment of RMI but does not provide notice of reinstatement of export privileges for RMI pursuant to the statutory requirements of § 38(g)(4) of the AECA and ITAR § 127.11. As required by the statute, the Department may not issue a license directly to RMI except as may be determined on a case-by-case basis after interagency consultations, a thorough review of the circumstances surrounding the conviction, and a finding that appropriate steps have been taken to mitigate any law enforcement concerns. Any determination by the Department regarding the reinstatement of export privileges for RMI will be made in accordance with these statutory and regulatory requirements and will be the subject of a separate notice. All otherwise eligible persons may engage in exports of RMI manufactured defense articles, incorporate RMI manufactured items into defense articles for export, or otherwise engage in transactions subject to the ITAR without providing prior written notification of RMI's involvement as otherwise required by ITAR § 127.1(d) and the transaction exception requirements of the **Federal Register** notice of statutory debarment (75 FR 54693).

Dated: February 4, 2019.

Andrea L. Thompson,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 2019–03595 Filed 3–1–19; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2019–0128]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Notice of Landing Area Proposal

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves gathering information from airport sponsors about any establishment, construction, alteration, or change to the status or use of an airport. The FAA uses this information to conduct airport airspace analyses to understand the impact of proposed actions on existing and planned operating procedures, determine potential hazardous effects, and identify any mitigating measures needed to enhance safe air navigation. Additionally, the information updates the aeronautical charts and maps airports having emergency landing or landmark values.

DATES: Written comments should be submitted by May 3, 2019.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Raymond Zee, Airport Engineering Division (AAS–100), Office of Airport Safety and Standards, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

By fax: 202–267–5383.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Raymond Zee by email at:

Raymond.Zee@faa.gov; phone: 202–267–7669.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0036.

Title: Notice of Landing Area Proposal.

Form Numbers: FAA Form 7480–1.

Type of Review: Renewal of an information collection.

Background: Title 14 Code of Federal Regulations Part 157, Notice of Construction, Alteration, Activation, and Deactivation of Airports, requires that each person who intends to establish, construct, deactivate, or change the status of an airport, runway, or taxiway notify the FAA of such activity. The FAA uses the information collected to determine the effect the proposed action will have on existing airports and on the safe and efficient use of airspace by aircraft, the effects on existing airspace or contemplated traffic patterns of neighboring airports, the effects on the existing airspace structure and projected programs of the FAA, and the effects that existing or proposed manmade objects (on file with the FAA) and natural objects within the affected area will have on the airport proposal. This information also updates aeronautical charts and maps airports having emergency landing or landmark values. The FAA collects this information via an online reporting tool available on the FAA website (FAA Form 7480–1).

Respondents: Approximately 350 applicants.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 1 hour.

Estimated Total Annual Burden: 350 hours.

Issued in Washington, DC, on February 26, 2019.

Raymond Zee,

Civil Engineer, Airport Engineering Division, Office of Airport Safety and Standards.

[FR Doc. 2019–03724 Filed 3–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2019–0011]

Deepwater Port License Application: SPOT Terminal Services LLC (SPOT).

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice of application.

SUMMARY: The Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announce they have received an application for the licensing of a deepwater port and that the application contains information sufficient to commence processing. This notice summarizes the applicant's plans and the procedures that will be followed in considering the application.

DATES: The Deepwater Port Act of 1974, as amended, requires at least one public hearing on this application to be held in the designated Adjacent Coastal State(s) not later than 240 days after publication of this notice, and a decision on the application not later than 90 days after the final public hearing(s).

ADDRESSES: The public docket for the SPOT deepwater port license application is maintained by the U.S. Department of Transportation, Docket Management Facility, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

The license application is available for viewing at the *Regulations.gov* website: *http://www.regulations.gov* under docket number MARAD–2019–0011.

We encourage you to submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov.* If you submit your comments electronically, it is not necessary to also submit a hard copy. If you cannot submit material using *http://www.regulations.gov,* please contact either Mr. Efrain Lopez, USCG or Ms. Yvette M. Fields, MARAD, as listed in the following **FOR FURTHER INFORMATION CONTACT** section of this document. This section provides alternate instructions for submitting written comments. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted. Anonymous comments will be accepted. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. The Federal Docket Management Facility's telephone number is 202–366–9317 or 202–366–9826, the fax number is 202–493–2251.

FOR FURTHER INFORMATION CONTACT: Mr. Efrain Lopez, U.S. Coast Guard, telephone: 202–372–1437, email: *Efrain.Lopez1@uscg.mil,* or Ms. Yvette M. Fields, Maritime Administration, telephone: 202–366–0926, email: *Yvette.Fields@dot.gov.* For questions regarding viewing the Docket, call Docket Operations, telephone: 202–366–9317 or 202–366–9826.

SUPPLEMENTARY INFORMATION:

Receipt of Application

On January 31, 2019, MARAD and USCG received an application from SPOT Terminal Services LLC (SPOT) for Federal authorizations required for a license to own, construct, and operate a deepwater port for the export of oil as authorized by the Deepwater Port Act of 1974, as amended, 33 U.S.C. 1501 *et seq.* (the Act), and implemented under 33 Code of Federal Regulations (CFR) Parts 148, 149, and 150. After a coordinated completeness review by MARAD, the USCG, and other cooperating Federal agencies, the application is deemed complete and contains information sufficient to initiate processing.

Background

The Act defines a deepwater port as any fixed or floating manmade structure other than a vessel, or any group of such structures, that are located beyond State seaward boundaries and used or intended for use as a port or terminal for the transportation, storage, and further handling of oil or natural gas for transportation to, or from, any State. A deepwater port includes all components and equipment, including pipelines, pumping or compressor stations, service platforms, buoys, mooring lines, and similar facilities that are proposed as part of a deepwater port to the extent they are located seaward of the high-water mark.

The Secretary of Transportation delegated to the Maritime Administrator authorities related to licensing deepwater ports (49 CFR 1.93(h)). Statutory and regulatory requirements for processing applications and licensing appear in 33 U.S.C. 1501 *et seq.* and 33 CFR part 148. Under delegations from, and agreements between, the Secretary of Transportation and the Secretary of Homeland Security, applications are jointly processed by MARAD and USCG. Each application is considered on its merits.

In accordance with 33 U.S.C. 1504(f) for all applications, MARAD and the USCG, working in cooperation with other involved Federal agencies and departments, shall comply with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*). The U.S. Environmental Protection Agency (EPA), the U.S. Army Corps of Engineers (USACE), the National Oceanic and Atmospheric Administration (NOAA), the Bureau of Ocean Energy Management (BOEM), the Bureau of Safety and Environmental Enforcement (BSEE), and the Pipeline and Hazardous Materials Safety Administration

(PHMSA), among others, participate in the processing of deepwater port applications and assist in the NEPA process as described in 40 CFR 1501.6. Each agency may participate in scoping and/or other public meeting(s) and may adopt the MARAD/USCG prepared environmental impact review for purposes of their jurisdictional permitting processes, to the extent applicable. Comments related to this deepwater port application addressed to the EPA, USACE, or other Federal agencies should note the Federal docket number, MARAD–2019–0011. Each comment will be incorporated into the Department of Transportation (DOT) docket and considered as the environmental impact analysis is developed to ensure consistency with the NEPA process.

All connected actions, permits, approvals and authorizations will be considered during the processing of SPOT's deepwater port license application.

MARAD, in issuing this Notice of Application pursuant to 33 U.S.C. 1504(c), must designate as an ''Adjacent Coastal State'' any coastal state which (A) would be directly connected by pipeline to a deepwater port as proposed in an application, or (B) would be located within 15 nautical miles of any such proposed deepwater port (see 33 U.S.C. 1508(a)(1)). Pursuant to the criteria provided in the Act, Texas is the designated Adjacent Coastal State for this application. Other states may request from the Maritime Administrator designation as an Adjacent Coastal State in accordance with 33 U.S.C. 1508(a)(2).

The Act directs that at least one public hearing take place in each Adjacent Coastal State, in this case, Texas. Additional public meetings may be conducted to solicit comments for the environmental analysis to include public scoping meetings, or meetings to discuss the Draft and Final environmental impact documents prepared in accordance with NEPA.

MARAD, in coordination with the USCG, will publish additional **Federal Register** notices with information regarding these public meeting(s) and hearing(s) and other procedural milestones, including the NEPA environmental impact review. The Maritime Administrator's decision, and other key documents, will be filed in the public docket at docket number MARAD–2019–0011.

The Deepwater Port Act imposes a strict timeline for processing an application. When MARAD and USCG determine that an application is complete (*i.e.,* contains information sufficient to commence processing), the Act directs that all public hearings on the application be concluded within 240 days from the date the Notice of Application is published.

Within 45 days after the final hearing, the Governor of the Adjacent Costal State, in this case the Governor of Texas, may notify MARAD of his approval, approval with conditions, or disapproval of the application. If such approval, approval with conditions, or disapproval is not provided to the Maritime Administrator by that time, approval shall be conclusively presumed. MARAD may not issue a license without the explicit or presumptive approval of the Governor of the Adjacent Coastal State. During this 45-day period, the Governor may also notify MARAD of inconsistencies between the application and State programs relating to environmental protection, land and water use, and coastal zone management. In this case, MARAD may condition the license to make it consistent with such state programs (33 U.S.C. 1508(b)(1)). MARAD will not consider written approvals or disapprovals of the application from the Governor of the Adjacent Coastal State until after the final public hearing is complete and the 45-day period commences.

The Maritime Administrator must render a decision on the application within 90 days after the final hearing.

In accordance with section 33 U.S.C. 1504(d), MARAD is required to designate an application area for a deepwater port application intended to transport oil. Section 1504(d)(2) provides MARAD the discretion to establish a reasonable application area constituting the geographic area in which only one deepwater port may be constructed and operated. MARAD has consulted with USCG in developing SPOT's application area and designates an application area encompassing the deepwater port that is a circle having a radius of no less than three-and-three-tenths (3.30) nautical miles centered at SPOT's proposed platform, latitude N 28°27′59.22″ and longitude W 95°07′ 24.49″, and 0.25 nautical miles on either side of SPOT's proposed pipeline route between the terminal and the shore. Any person interested in applying for the ownership, construction, and operation of a deepwater port within this designated application area must file with MARAD (see **FOR FURTHER INFORMATION CONTACT**) a notice of intent to file an application for the construction and operation of a deepwater port not later than 60 days after the date of publication of this notice, and shall submit a completed application no later than 90 days after publication of this notice.

Should a favorable record of decision be rendered and license be issued, MARAD may include specific conditions related to design, construction, operations, environmental permitting, monitoring and mitigations, and financial responsibilities. If a license is issued, USCG in coordination with other agencies as appropriate, would review and approve the deepwater port's engineering, design, and construction; operations/security procedures; waterways management and regulated navigation areas; maritime safety and security requirements; risk assessment; and compliance with domestic and international laws and regulations for vessels that may call on the port. The deepwater port would be designed, constructed and operated in accordance with applicable codes and standards.

In addition, installation of pipelines and other structures may require permits under Section 404 of the Clean Water Act and Section 10 of the Rivers and Harbors Act, which are administered by the USACE.

Permits from the EPA may also be required pursuant to the provisions of the Clean Air Act, as amended, and the Clean Water Act, as amended.

Summary of the Application

SPOT is proposing to construct, own, and operate a deepwater port terminal in the Gulf of Mexico to export domestically produced crude oil. Use of the deepwater port would include the loading of various grades of crude oil at flow rates of up to 85,000 barrels per hour (bph). The SPOT deepwater port would allow for up to two (2) Very Large Crude Carriers (VLCCs) or other crude oil carriers to moor at single point mooring (SPM) buoys and connect with the deepwater port via floating connecting crude oil hoses and a floating vapor recovery hose. The maximum frequency of loading VLCCs or other crude oil carriers would be 2 million barrels per day, 365 days per year.

The overall project would consist of offshore and marine components as well as onshore components as described below.

The SPOT deepwater port offshore and marine components would consist of the following:

- One (1) fixed offshore platform with eight (8) piles in Galveston Area Outer Continental Shelf lease block 463, approximately 27.2 to 30.8 nautical miles off the coast of Brazoria County, Texas in a water depth of approximately 115 feet. The fixed offshore platform

would be comprised of four (4) decks including: A sump deck with shut-down valves and open drain sump; a cellar deck with pig launchers and receivers, generators, and three (3) vapor combustion units; a main deck with a lease automatic custody transfer (LACT) unit, oil displacement prover loop, living quarters, electrical and instrument building, and other ancillary equipment; and a laydown deck with a crane laydown area.

• Two (2) single point mooring buoys (SPMs), each having: Two (2) 24-inch inside diameter crude oil underbuoy hoses interconnecting with the crude oil pipeline end manifold (PLEM); two (2) 24-inch inside diameter floating crude oil hoses connecting the moored VLCC or other crude oil carrier for loading to the SPM buoy; one (1) 24-inch inside diameter vapor recovery underbuoy hose interconnecting with the vapor recovery PLEM; and one (1) 24-inch inside diameter floating vapor recovery hose to connect to the moored VLCC or other crude oil carrier for loading. The floating hoses would be approximately 800 feet in length and rated for 300 psig (21-bar). Each floating hose would contain an additional 200 feet of 16-inch ''tail hose'' that is designed to be lifted and robust enough for hanging over the edge railing of the VLCC or other crude oil carrier. The underbuoy hoses would be approximately 160 feet in length and rated for 300 psig (21-bar).

• Four (4) PLEMs would provide the interconnection between the pipelines and the SPM buoys. Each SPM buoy would have two (2) PLEMs—one (1) PLEM for crude oil and one (1) PLEM for vapor recovery. Each crude oil loading PLEM would be supplied with crude oil by two (2) 30-inch outside diameter pipelines, each approximately 0.66 nautical miles in length. Each vapor recovery PLEM would route recovered vapor from the VLCC or other crude oil carrier through the PLEM to the three (3) vapor combustion units located on the platform topside via two (2) 16-inch outside diameter vapor recovery pipelines, each approximately 0.66 nautical miles in length.

• Two (2) co-located 36-inch outside diameter, 40.8-nautical mile long crude oil pipelines would be constructed from the shoreline crossing in Brazoria County, Texas, to the SPOT deepwater port for crude oil delivery. These pipelines, in conjunction with 12.2 statute miles of new-build onshore pipelines (described below), would connect the onshore crude oil storage facility and pumping station (Oyster Creek Terminal) to the offshore SPOT deepwater port. The crude oil would be metered at the offshore platform. Pipelines would be bi-directional for the purposes of maintenance, pigging, changing crude oil grades, or evacuating the pipeline with water.

The SPOT deepwater port onshore storage and supply components would consist of the following:

• New equipment and piping at the existing Enterprise Crude Houston (ECHO) Terminal to provide interconnectivity with the crude oil supply network for the SPOT Project. This would include the installation of four (4) booster pumps, one (1) measurement skid, and four (4) crude oil pumps.

• An interconnection between the existing Rancho II pipeline and the proposed ECHO to Oyster Creek pipeline consisting of a physical connection as well as ultrasonic measurement capability for pipeline volumetric balancing purposes.

• The proposed Oyster Creek Terminal located in Brazoria County, Texas, on approximately 140 acres of land consisting of seven (7) aboveground storage tanks, each with a total storage capacity of 685,000 barrels (600,000 barrels working storage capacity), for a total onshore storage capacity of approximately 4.8 million barrels (4.2 million barrels working storage) of crude oil. The Oyster Creek Terminal also would include: Six (6) electric-driven mainline crude oil pumps; four (4) electric-driven booster crude oil pumps (two (2) per pipeline), working in parallel to move crude oil from the storage tanks through the measurement skids; two (2) crude oil pipeline pig launchers/receivers; one (1) crude oil pipeline pig receiver; two (2) measurement skids for measuring incoming crude oil—one (1) skid located at the incoming pipeline from the existing Enterprise Crude Houston (ECHO) Terminal, and one (1) skid installed and reserved for a future pipeline connection; two (2) measurement skids for measuring departing crude oil; three (3) vapor combustion units—two (2) permanent and one (1) portable; and ancillary facilities to include electrical substation, office, and warehouse buildings.

• Three onshore crude oil pipelines would be constructed onshore to support the SPOT deepwater port. These would include: One (1) 50.1 statute mile long 36-inch crude oil pipeline from the existing ECHO Terminal to the Oyster Creek Terminal. This pipeline would be located in Harris County and Brazoria County, Texas; two (2) 12.2 statute mile long, co-located 36-inch crude oil export pipelines from the Oyster Creek Terminal to the shore crossing where these would join the above described subsea pipelines supplying the SPOT deepwater port. These pipelines would be located in Brazoria County, Texas.

Privacy Act

DOT posts comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 33 U.S.C. 1501, *et seq.*; 49 CFR 1.93(h))

* * * * *

Dated: February 27, 2019.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2019–03803 Filed 3–1–19; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Interagency Appraisal Complaint Form

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The Office of the Comptroller of the Currency (OCC), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on an information collection renewal as required by the Paperwork Reduction Act of 1995.

An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. The OCC is soliciting comment concerning the renewal of its information collection titled ''Interagency Appraisal Complaint Form.''

DATES: Comments must be received by May 3, 2019.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–314, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0314'' in your comment. In general, the OCC will publish your comment on *www.reginfo.gov* without change, including any business or personal information that you provide, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0314, U.S. Office of Management and Budget, 725 17th Street NW, #10235, Washington, DC 20503 or by email to *oira_submission@omb.eop.gov.*

You may review comments and other related materials that pertain to this information collection [1] following the close of the 30-day comment period for this notice by any of the following methods:

- *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0314'' or ''Interagency Appraisal Complaint Form.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.
- For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.
- *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC requests that OMB extend its approval of this collection.

Description: Section 1473(p) of the Dodd-Frank Wall Street Reform and Consumer Protection Act [2] provides that if the Appraisal Subcommittee (ASC) of the Federal Financial Institutions Examination Council (FFIEC) determines, six months after enactment of that section (*i.e.,* January 21, 2011), that no national hotline exists to receive complaints of non-compliance with appraisal independence standards and Uniform Standards of Professional Appraisal Practice (USPAP), then the ASC shall establish and operate such a hotline (ASC Hotline). The ASC Hotline shall include a toll-free telephone number and an email address. Section 1473(p) further directs the ASC to refer complaints received through the ASC Hotline to the appropriate government bodies for further action, which may include referrals to OCC, the Federal Reserve Board (Board), the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), the Consumer Financial Protection Bureau (CFPB), and state agencies. The ASC determined that a national appraisal hotline did not exist at a meeting held on January 12, 2011, and a notice of that determination was published in the **Federal Register** on January 28, 2011, (76 FR 5161). As a result, the ASC established a hotline to refer complaints to appropriate federal and state regulators.

Representatives from the OCC, the Board, the FDIC, the NCUA (Agencies), and the CFPB met and established a process to facilitate the referral of complaints received through the ASC Hotline to the appropriate federal financial institution regulatory agency or agencies. The Agencies developed the Interagency Appraisal Complaint Form to collect information necessary to take further action on the complaint. The CFPB incorporated the process into one of their existing systems.

The Interagency Appraisal Complaint Form was developed for use by those who wish to file a formal, written complaint that an entity subject to the jurisdiction of one or more of the Agencies has failed to comply with the appraisal independence standards or USPAP. The Interagency Appraisal Complaint Form is designed to collect information necessary for the Agencies to take further action on a complaint from an appraiser, other individual, financial institution, or other entities. The Agencies use the information to take further action on the complaint to the extent the complaint relates to an issue within their jurisdiction.

OMB Control No.: 1557–0314.

Estimated Number of Respondents: 100.

Estimated Burden per Response: 0.5 hours.

Estimated Total Annual Burden: 50 hours.

On October 26, 2018, the OCC issued a notice for 60 days of comment concerning this collection, 83 FR 54174. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the collection of information;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

[1] On October 26, 2018, the OCC published a 60-day notice for this information collection, 83 FR 54174.

[2] Dodd-Frank Wall Street Reform and Consumer Protection Act section 1473, Public Law 111–203, 124 Stat. 1376, July 21, 2010; 12 U.S.C. 3351(i).

Dated: February 26, 2019.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2019–03843 Filed 3–1–19; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008; Technical Amendment to External Review for Multi-State Plan Program.

DATES: Written comments should be received on or before May 3, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008; Technical Amendment to External Review for Multi-State Plan Program.

OMB Number: 1545–2165.

Regulation Project Number: TD 9640.

Abstract: This document contains previously approved final rules implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008, which requires parity between mental health or substance use disorder benefits and medical/surgical benefits with respect to financial requirements and treatment limitations under group health plans and group and individual health insurance coverage.

Current Actions: The increase in hour burden is associated with the ICRs related to the new draft model disclosure request form the Department is issuing in order to meet the MHPAEA-related requirements in the 21st Century Cures Act.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 1,154,036.

Estimated Time per Respondent: 1 minute.

Estimated Total Annual Burden Hours: 26,912.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 26, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03728 Filed 3–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning certain cash or deferred arrangements and employee and matching contributions under employee plans, and retirement plans; cash or deferred arrangements.

DATES: Written comments should be received on or before May 3, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certain Cash or Deferred Arrangements and Employee and Matching Contributions under Employee Plans: Retirement Plans; Cash or Deferred Arrangements.

OMB Number: 1545–1069.

Form Number: EE–175–86; Reg–108639–99.

Abstract: This regulation provides the public with the guidance needed to comply with sections 40(k), 401(m), and 4979 of the Internal Revenue Code. The regulation affects sponsors of plans that contain cash or deferred arrangements of employee or matching contributions, and employees who are entitled to make elections under these plans.

Current Actions: There are no changes to the existing regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit institutions, farms, and state, local, or tribal governments.

Estimated Number of Respondents: 355,500.

Estimated Time per Respondent: 3 hours.

Estimated Total Annual Burden Hours: 1,060,000.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 25, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03729 Filed 3–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Monday, March 18, 2019 and Tuesday, March 19, 2019.

FOR FURTHER INFORMATION CONTACT: Robert Rosalia at 1–888–912–1227 or (718) 834–2203.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Monday, March 18, 2019, from 1:00 p.m. to 5:00 p.m. Eastern Time and Tuesday, March 19, 2019, from 8:00 a.m. until 5:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Robert Rosalia. For more information please contact Robert Rosalia at 1–888–912–1227 or (718) 834–2203, or write TAP Office, 2 Metrotech Center, 100 Myrtle Avenue, Brooklyn, NY 11201 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: February 26, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–03800 Filed 3–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning empowerment zone employment credit.

DATES: Written comments should be received on or before May 3, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Empowerment Zone Employment Credit.

OMB Number: 1545–1444.

Form Number: 8844.

Abstract: Employers who hire employees who live and work in one of the eleven designated empowerment zones can receive a tax credit for the first $15,000 of wages paid to each employee.

Current Actions: There are no changes being made to the burden associated with the collection tool at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, farms and non-profit institutions.

Estimated Number of Respondents: 26,400.

Estimated Time per Respondent: 9 hours.

Estimated Total Annual Burden Hours: 237,600.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of

information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 25, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03730 Filed 3–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning revocation of election filed under property transferred in connection with performance of services to include gross income in year of transfer.

DATES: Written comments should be received on or before May 3, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *Kerry.Dennis@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Revocation of Election filed under I.R.C. 83(b).

OMB Number: 1545–2018.

Form Number: Rev. Proc. 2006–31.

Abstract: This revenue procedure sets forth the procedures to be followed by individuals who wish to request permission to revoke the election they made under section 83(b).

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and Households.

Estimated Number of Respondents: 200.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 400.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 25, 2019.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2019–03731 Filed 3–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, March 21, 2019 and Friday, March 22, 2019.

FOR FURTHER INFORMATION CONTACT: Otis Simpson at 1–888–912–1227 or 202–317–3332.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Communications Notices and Correspondence Project Committee will be held Thursday, March 21, 2019, from 8:00 a.m. to 5:00 p.m. Eastern Time and Friday, March 22, 2019, from 8:00 a.m. until 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Otis Simpson. For more information please contact Otis Simpson at 1–888–912–1227 or 202–317–3332, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: February 26, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–03801 Filed 3–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, March 21, 2019 and Friday, March 22, 2019.

FOR FURTHER INFORMATION CONTACT: Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Taxpayer Assistance Center Project Committee will be held Thursday, March 21, 2019, from 8:00 a.m. to 5:00 p.m. Eastern Time and Friday, March 22, 2019, from 8:00 a.m. until 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Matthew O'Sullivan. For more information please contact Matthew O'Sullivan at 1–888–912–1227 or (510) 907–5274, or write TAP Office, 1301 Clay Street, Oakland, CA 94612–5217 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: February 26, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–03797 Filed 3–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Line Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Line Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, March 21, 2019 and Friday, March 22, 2019.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Line Project Committee will be held Thursday, March 21, 2019, from 8:00 a.m. to 5:00 p.m. Eastern Time and Friday, March 22, 2019, from 8:00 a.m. until 12:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Rosalind Matherne. For more information please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda will include various IRS issues.

Dated: February 26, 2019.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2019–03798 Filed 3–1–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Homeless Veterans; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that a meeting of the Advisory Committee on Homeless Veterans will be held April 3–4, 2019. The meeting sessions will take place at the Department of Veterans Affairs Central Office at 810 Vermont Avenue NW, Sonny Montgomery Conference Room 230, Washington, DC 20420.

The purpose of the Committee is to provide the Secretary of Veterans Affairs with an on-going assessment of the effectiveness of the policies, organizational structures, and services of VA in assisting Veterans at-risk and experiencing homelessness. The Committee shall assemble and review information related to the needs of homeless Veterans and provide advice on the most appropriate means of providing assistance to that subset of the Veteran population. The Committee will make recommendations to the Secretary regarding such activities.

On Wednesday, April 3, 2019, the Committee will convene an open session rom 8:00 a.m. to 5:00 p.m. (Eastern Standard Time). On Thursday, April 4, 2019, the Committee will convene an open session from 8:00 a.m. to 3:00 p.m. (Eastern Standard Time). The agenda for both meetings will include briefings from officials at VA and other federal agencies regarding services for homeless Veterans. The Committee will also discuss topics for its annual report and recommendations to the Secretary of Veterans Affairs.

No time will be allocated at this meeting for receiving oral presentations from the public. Interested parties should provide written comments on issues affecting homeless Veterans for review by the Committee to Mr. Anthony Love, Designated Federal Officer, Veterans Health Administration Homeless Programs Office (10NC1), Department of Veterans Affairs, 811 Vermont Avenue NW (10NC1), Washington, DC 20420, or via email at *Anthony.Love@va.gov* and *Leisa.Davis@va.gov.*

Members of the public who wish to attend should contact *Anthony.Love@va.gov* (202) 461–1902 and *Leisa.Davis@va.gov* (202) 632–8588 of the Veterans Health Administration, Homeless Programs Office no later than March 18, 2019, to provide their name, professional affiliation, email address, and phone number. There will also be a call-in number at 1–800–767–1750; Access Code: 50653#. Attendees who require reasonable accommodations should also state so in their requests. Please arrive to VA Central Office at least 20 (twenty) minutes before the meeting start time to clear the building security checkpoint.

Dated: February 27, 2019.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2019–03799 Filed 3–1–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0128]

Agency Information Collection Activity Under OMB Review: Notice of Lapse, Notice of Past Due Payment

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before April 3, 2019.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov,* or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0128'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Danny S. Green at (202) 421–1354. Please refer to ''OMB Control No. 2900–0128'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 44 U.S.C. 3501–21.

Title: Notice of Lapse, Notice of Past Due Payment VA Form 29–389 and VA Form 29–389–1.

OMB Control Number: 2900–0128.

Type of Review: Extension of a previously approved collection.

Abstract: These forms are used by the policyholder to reinstate a lapsed life insurance policy. The information requested is authorized by law, 38 CFR Section 8.11.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 83 FR 32954 on July 16, 2018 page 32954.

Affected Public: Individuals or Households.

Estimated Annual Burden: 4,281.

Estimated Average Burden per Respondent: 11 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 23,352.

By direction of the Secretary.

Danny S. Green,

VA Interim Clearance Officer, Office of Quality, Privacy and Risk, Department of Veterans Affairs.

[FR Doc. 2019–03789 Filed 3–1–19; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Family, Caregiver, and Survivor Advisory Committee, Notice of Meeting Amended

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the Veterans' Family, Caregiver, and Survivor Advisory Committee will meet on March 26–27, 2019. The meeting will be held at the Department of Veterans Affairs, 810 Vermont Avenue NW, Room 230, Washington, DC 20420. Both sessions will begin at 9:00 a.m. (EST) each day. The session on March 26 will adjourn at approximately 5:00 p.m. The session on the March 27 will adjourn at approximately 3:00 p.m. The meetings are open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on matters related to: Veterans' families, caregivers, and survivors across all generations, relationships, and Veterans status; the use of VA care and benefits services by Veterans' families, caregivers, and survivors, and possible expansion of such care and benefits services; Veterans' family, caregiver, and survivor experiences; VA policies, regulations, and administrative requirements related to the transition of Servicemembers from the Department of Defense (DoD) to enrollment in VA that impact Veterans' families, caregivers, and survivors; and factors that influence access to, quality of, and accountability for services and benefits for Veterans' families, caregivers, and survivors.

On March 26 and 27, the agenda will include information on the pilot research from the Center for Excellence, updates from the Veterans Experience Office (VEO) White House Hotline (regarding comments from Veterans' families, caregivers, and survivors), an update on the Mission Act Implementation and Expansion of the Stipend Program to Pre-9/11/Inclusive Care; update on Tragedy Assistance Program (TAPS) and their collaboration with VA's Research Advisory Committee on Gulf War Veterans' Illnesses; and updates from the Office of Suicide Prevention and Office of Survivors. There will be opening remarks from VA senior leaders including the Chief Veterans Experience Officer and the Committee Chair and a presentation on the Recommendations this Committee submitted in November 2018. Committee members will also discuss the committee work plan and future activities. Public comments will be received at 4:00 p.m. to 5:00 p.m. on March 26, 2019.

Individuals wishing to speak should contact Dr. Betty Moseley Brown at *Betty.MoseleyBrown@va.gov* and are requested to submit a 1–2 page summary of their comments for inclusion in the official meeting record. In the interest of time, each speaker will be held to a 5-minute time limit.

Because the meeting is being held in a government building, a photo I.D. must be presented at the Guard's Desk as a part of the clearance process. To prevent delays, you should allow an additional 30 minutes before the meeting begins to clear security. If you are interested in attending, please submit your name to Betty Moseley Brown by March 22, 2019 to help expedite the security clearance process. Any member of the public seeking additional information should contact Betty Moseley Brown at (202) 465–6199 or at *Betty.MoseleyBrown@va.gov.*

Dated: February 27, 2019.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2019–03771 Filed 3–1–19; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 84 Monday,

No. 42 March 4, 2019

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, 422, *et al.*

45 CFR Parts 156, 170, and 171

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program; Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171

RIN 0955–AA01

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions would advance interoperability and support the access, exchange, and use of electronic health information. The proposed rule would also modify the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on May 3, 2019.

ADDRESSES: You may submit comments, identified by RIN 0955–AA01, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. *http://www.regulations.gov.*
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.
- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Enhancing the Public Comment Experience: To facilitate public comment on this proposed rule, a copy will be made available in Microsoft Word format on ONC's website (*http://www.healthit.gov*). We believe this version will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally, a separate document (''public comment template'') will also be made available on ONC's website (*http://www.healthit.gov*) for the public to use in providing comments on the proposed rule. This document is meant to provide the public with a simple and organized way to submit comments on proposals and respond to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments, or to use it as an addendum to narrative cover pages. We believe that use of the document may facilitate our review and understanding of the comments received. The public comment template will be available shortly after the proposed rule publishes in the **Federal Register**. This short delay will permit the appropriate citation in the public comment template to pages of the published version of the proposed rule.

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
A. Purpose of Regulatory Action
B. Summary of Major Provisions and Clarifications
1. Deregulatory Actions for Previous Rulemakings
2. Updates to the 2015 Edition Certification Criteria
a. Adoption of the United States Core Data for Interoperability as a Standard
b. Electronic Prescribing
c. Clinical Quality Measures—Report
d. Electronic Health Information Export
e. Application Programming Interfaces
f. Privacy and Security Transparency Attestations
g. Data Segmentation for Privacy and Consent Management
3. Modifications to the ONC Health IT Certification Program
4. Health IT for the Care Continuum
5. Conditions and Maintenance of Certification
6. Information Blocking
C. Costs and Benefits
II. Background
A. Statutory Basis
1. Standards, Implementation Specifications, and Certification Criteria
2. Health IT Certification Program(s)
B. Regulatory History
1. Standards, Implementation Specifications, and Certification Criteria Rules
2. ONC Health IT Certification Program Rules
III. Deregulatory Actions for Previous Rulemakings
A. Background
1. History of Burden Reduction and Regulatory Flexibility
2. Executive Orders 13771 and 13777

B. Proposed Deregulatory Actions
1. Removal of Randomized Surveillance Requirements
2. Removal of the 2014 Edition From the Code of Federal Regulations
3. Removal of the ONC-Approved Accreditor From the Program
4. Removal of Certain 2015 Edition Certification Criteria and Standards
a. 2015 Edition Base EHR Definition Certification Criteria
b. Drug-Formulary and Preferred Drug Lists
c. Patient-Specific Education Resources
d. Common Clinical Data Set Summary Record—Create; and Common Clinical Data Set Summary Record—Receive
e. Secure Messaging
5. Removal of Certain ONC Health IT Certification Program Requirements
a. Limitations Disclosures
b. Transparency and Mandatory Disclosures Requirements
6. Recognition of Food and Drug Administration Processes
a. FDA Software Pre-Certification Pilot Program
b. Development of Similar Independent Program Processes—Request for Information
IV. Updates to the 2015 Edition Certification Criteria
A. Standards and Implementation Specifications
1. National Technology Transfer and Advancement Act
2. Compliance with Adopted Standards and Implementation Specifications
3. ''Reasonably Available'' to Interested Parties
B. Revised and New 2015 Edition Criteria
1. The United States Core Data for Interoperability Standard (USCDI)
a. USCDI 2015 Edition Certification Criteria
b. USCDI Standard—Data Classes Included
c. USCDI Standard—Relationship to Content Exchange Standards and Implementation Specifications
d. Clinical Notes C–CDA Implementation Specification
2. Electronic Prescribing Criterion
3. Clinical Quality Measures—Report Criterion
4. Electronic Health Information Export Criterion
a. Patient Access
b. Transitions Between Health IT Systems
c. Scope of EHI
d. Export Format
e. Initial Step to Persistent Access to All of a Patient's EHI
f. Timeframes
g. Replaces the 2015 Edition ''Data Export'' Criterion in the 2015 Edition Base EHR Definition
5. Standardized API for Patient and Population Services Criterion
6. Privacy and Security Transparency Attestations Criteria
a. Background
b. Encrypt Authentication Credentials
c. Multi-factor Authentication
7. Data Segmentation for Privacy and Consent Management Criteria
a. Implementation With the Consolidated CDA Release 2.1
b. Implementation With FHIR Standard
C. Unchanged 2015 Edition Criteria—Promoting Interoperability Programs Reference Alignment
V. Modifications to the ONC Health IT Certification Program
A. Corrections
1. Auditable Events and Tamper Resistance
2. Amendments
3. View, Download, and Transmit to 3rd Party
4. Integrating Revised and New Certification Criteria Into the 2015 Edition Privacy and Security Certification Framework
B. Principles of Proper Conduct for ONC–ACBs
1. Records Retention
2. Conformance Methods for Certification Criteria
3. ONC-ACBs to Accept Test Results From Any ONC-ATL in Good Standing
4. Mandatory Disclosures and Certifications
C. Principles of Proper Conduct for ONC–ATLs—Records Retention
VI. Health IT for the Care Continuum
A. Health IT for Pediatric Setting
1. Background and Stakeholder Convening
2. Recommendations for the Voluntary Certification of Health IT for Use in Pediatric Care
a. 2015 Edition Certification Criteria
b. New or Revised Certification Criteria in This Proposed Rule
B. Health IT and Opioid Use Disorder Prevention and Treatment—Request for Information
1. 2015 Edition Certification Criteria
2. Revised or New 2015 Edition Certification Criteria in This Proposed Rule
3. Emerging Standards and Innovations
4. Additional Comment Areas
VII. Conditions and Maintenance of Certification
A. Implementation
B. Provisions
1. Information Blocking
2. Assurances
a. Full Compliance and Unrestricted Implementation of Certification Criteria Capabilities
b. Certification to the ''Electronic Health Information Export'' Criterion
c. Records and Information Retention
d. Trusted Exchange Framework and the Common Agreement—Request for Information
3. Communications
a. Background and Purpose
b. Condition of Certification Requirements
c. Maintenance of Certification Requirements
4. Application Programming Interfaces
a. Statutory Interpretation and API Policy Principles
b. Key Terms
c. Proposed API Standards, Implementation Specifications, and Certification Criterion
d. Condition of Certification Requirements
e. Maintenance of Certification Requirements
f. 2015 Edition Base EHR Definition
5. Real World Testing
6. Attestations
7. EHR Reporting Criteria Submission
C. Compliance
D. Enforcement
1. ONC Direct Review of the Conditions and Maintenance of Certification Requirements
2. Review and Enforcement Only by ONC
3. Review Processes
a. Initiating Review and Health IT Developer Notice
b. Relationship with ONC–ACBs and ONC–ATLs
c. Records Access
d. Corrective Action
e. Certification Ban and Termination
f. Appeal
g. Suspension
h. Proposed Termination
4. Public Listing of Certification Ban and Terminations
5. Effect on Existing Program Requirements and Processes
6. Concurrent Enforcement by the Office of Inspector General
7. Applicability of Conditions and Maintenance of Certification Requirements for Self-Developers
VIII. Information Blocking
A. Statutory Basis
B. Legislative Background and Policy Considerations
1. Purpose of the Information Blocking Provision
2. Policy Considerations and Approach to the Information Blocking Provisions
C. Relevant Statutory Terms and Provisions
1. ''Required by Law''
2. Health Care Providers, Health IT Developers, Exchanges, and Networks
a. Health Care Providers
b. Health IT Developers of Certified Health IT
c. Networks and Exchanges
3. Electronic Health Information
4. Interests Promoted by the Information Blocking Provision
a. Access, Exchange, and Use of EHI
b. Interoperability Elements
5. Practices That May Implicate the Information Blocking Provision
a. Prevention, Material Discouragement, and Other Interference
b. Likelihood of Interference
c. Examples of Practices Likely To Interfere With Access, Exchange, or Use of EHI
6. Applicability of Exceptions
a. Reasonable and Necessary Activities
b. Treatment of Different Types of Actors
c. Establishing That Activities and Practices Meet the Conditions of an Exception
D. Proposed Exceptions to the Information Blocking Provision
1. Preventing Harm
2. Promoting the Privacy of EHI
3. Promoting the Security of EHI
4. Recovering Costs Reasonably Incurred
5. Responding to Requests That Are Infeasible
6. Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms
7. Maintaining and Improving Health IT Performance
E. Additional Exceptions—Request for Information

1. Exception for Complying With Common Agreement for Trusted Exchange
2. New Exceptions
F. Complaint Process
G. Disincentives for Health Care Providers—Request for Information
IX. Registries Request for Information
X. Patient Matching Request for Information
XI. Incorporation by Reference
XII. Response to Comments
XIII. Collection of Information Requirements
A. ONC–ACBs
B. Health IT Developers
XIV. Regulatory Impact Analysis
A. Statement of Need
B. Alternatives Considered
C. Overall Impact
1. Executive Orders 12866 and 13563—Regulatory Planning and Review Analysis
2. Executive Order 13771—Reducing Regulation and Controlling Regulatory Costs
a. Costs and Benefits
b. Accounting Statement and Table
3. Regulatory Flexibility Act
4. Executive Order 13132—Federalism
5. Unfunded Mandates Reform Act of 1995
6. Executive Order 13771 Reducing Regulation and Controlling Regulatory Costs
Regulation Text

I. Executive Summary

A. Purpose of Regulatory Action

ONC is responsible for the implementation of key provisions in Title IV of the 21st Century Cures Act (Cures Act) that are designed to advance interoperability; support the access, exchange, and use of electronic health information; and address occurrences of information blocking. This proposed rule would implement certain provisions of the Cures Act, including Conditions and Maintenance of Certification requirements for health information technology (health IT) developers, the voluntary certification of health IT for use by pediatric health providers, and reasonable and necessary activities that do not constitute information blocking. In addition, the proposed rule would implement parts of section 4006(a) of the Cures Act to support patient access to their electronic health information (EHI), such as making a patient's EHI more electronically accessible through the adoption of standards and certification criteria and the implementation of information blocking policies that support patient electronic access to their health information at no cost. Additionally, the proposed rule would modify the 2015 Edition health IT certification criteria and ONC Health IT Certification Program (Program) in other ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

In addition to fulfilling the Cures Act's requirements, the proposed rule would contribute to fulfilling Executive Order (E.O.) 13813. The President issued E.O. 13813 on October 12, 2017, to promote health care choice and competition across the United States. Section 1(c) of the E.O., in relevant part, states that government rules affecting the United States health care system should re-inject competition into the health care markets by lowering barriers to entry and preventing abuses of market power. Section 1(c) also states that government rules should improve access to and the quality of information that Americans need to make informed health care decisions. For example, as mentioned above, the proposed rule focuses on establishing Application Programming Interfaces (APIs) for several interoperability purposes, including patient access to their health information without special effort. The API approach also supports health care providers having the sole authority and autonomy to unilaterally permit connections to their health IT through certified API technology the health care providers have acquired. In addition, the proposed rule provides ONC's interpretation of the information blocking definition as established in the Cures Act and the application of the information blocking provision by identifying reasonable and necessary activities that would not constitute information blocking. Many of these activities focus on improving patient and health care provider access to electronic health information and promoting competition.

B. Summary of Major Provisions and Clarifications

1. Deregulatory Actions for Previous Rulemakings

Since the inception of the Program, we have aimed to implement and administer the Program in the least burdensome manner that supports our policy goals. Throughout the years, we have worked to improve the Program with a focus on ways to reduce burden, offer flexibility to both developers and providers, and support innovation. This approach has been consistent with the principles of Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), which instructs agencies to ''determine whether any [agency] regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.'' To that end, we have historically, where feasible and appropriate, taken measures to reduce burden within the Program and make the Program more effective, flexible, and streamlined.

ONC has reviewed and evaluated existing regulations to identify ways to administratively reduce burden and implement deregulatory actions through guidance. In this proposed rule, we also propose potential new deregulatory actions that will reduce burden for health IT developers, providers, and other stakeholders. We propose six deregulatory actions in section III.B: (1) Removal of a threshold requirement related to randomized surveillance which allows ONC-Authorized Certification Bodies (ONC–ACBs) more flexibility to identify the right approach for surveillance actions, (2) removal of the 2014 Edition from the Code of Federal Regulations (CFR), (3) removal of the ONC-Approved Accreditor (ONC–AA) from the Program, (4) removal of certain 2015 Edition certification criteria, (5) removal of certain Program requirements, and (6) recognition of relevant Food and Drug Administration certification processes with a request for comment on the potential development of new processes for the Program.

2. Updates to the 2015 Edition Certification Criteria

This rule proposes to update the 2015 Edition by not only proposing criteria for removal, but by proposing to revise and add new certification criteria that would establish the capabilities and related standards and implementation specifications for the certification of health IT.

a. Adoption of the United States Core Data for Interoperability (USCDI) as a Standard

As part of ONC's continued efforts to assure the availability of a minimum baseline of data classes that could be commonly available for interoperable exchange, we adopted the 2015 Edition ''Common Clinical Data Set'' (CCDS) definition and used the CCDS shorthand in several certification criteria. However, the CCDS definition also began to be colloquially used for many different purposes. As the CCDS definition's relevance grew outside of its regulatory context, it became a symbolic and practical limit to the industry's collective interests to go beyond the CCDS data for access, exchange, and use. In addition, as we move further towards value-based care, the need for the inclusion of additional data classes that go beyond clinical data is necessary. In order to advance interoperability, we propose to remove the CCDS definition and its references

from the 2015 Edition and replace it with the ''United States Core Data for Interoperability.'' We propose to adopt the USCDI as a standard, naming USCDI Version 1 (USCDI v1) in § 170.213 and incorporating it by reference in § 170.299. The USCDI standard, if adopted, would establish a set of data classes and constituent data elements that would be required to be exchanged in support of interoperability nationwide. To achieve the goals set forth in the Cures Act, ONC intends to establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion. Once the USCDI is adopted in regulation naming USCDI v1, health IT developers would be allowed to take advantage of a flexibility under the Maintenance of Certification real world testing requirements, which we refer to as the ''Standards Version Advancement Process'' (described in section VII.B.5 of this proposed rule). The Standards Version Advancement Process would permit health IT developers to voluntarily implement and use a new version of an adopted standard, such as the USCDI, so long as the newer version was approved by the National Coordinator through the Standards Version Advancement Process for use in certification.

b. Electronic Prescribing

We propose to update the electronic prescribing (e-Rx) SCRIPT standard in 45 CFR 170.205(b) to NCPDP SCRIPT 2017071, which would result in a new e-Rx standard eventually becoming the baseline for certification. We also propose to adopt a new certification criterion in § 170.315(b)(11) for e-Rx to reflect these updated proposals. ONC and CMS have historically maintained complementary policies of maintaining aligned e-Rx and medical history (MH) standards to ensure that the current standard for certification to the electronic prescribing criterion permits use of the current Part D e-Rx and MH standards. This proposal is made to ensure such alignment as CMS recently finalized its Part D standards to NCPDP SCRIPT 2017071 for e-RX and MH, effective January 1, 2020 (83 FR 16440). In addition to continuing to reference the current transactions included in § 170.315(b)(3), in keeping with CMS' final rule, we also propose to require all of the NCPDP SCRIPT 2017071 standard transactions CMS adopted at 42 CFR 423.160(b)(2)(iv).

c. Clinical Quality Measures—Report

We propose to remove the HL7 Quality Reporting Document Architecture (QRDA) standard requirements from the 2015 Edition ''CQMs—report'' criterion in § 170.315(c)(3) and, in their place, require Health IT Modules to support the CMS QRDA Implementation Guide (IGs).[1] This would reduce the burden for health IT developers by only having to support one form of the QRDA standard rather than two forms (*i.e.,* the HL7 and CMS forms).

d. Electronic Health Information Export

We propose a new 2015 Edition certification criterion for ''electronic health information (EHI) export'' in § 170.315(b)(10), which would replace the 2015 Edition ''data export'' certification criterion (§ 170.315(b)(6)) and become part of the 2015 Edition Base EHR definition. The proposed criterion supports situations in which we believe that all EHI produced and electronically managed by a developer's health IT should be made readily available for export as a standard capability of certified health IT. Specifically, this criterion would: (1) Enable the export of EHI for a single patient upon a valid request from that patient or a user on the patient's behalf, and (2) support the export of EHI when a health care provider chooses to transition or migrate information to another health IT system. This criterion would also require that the export include the data format, made publicly available, to facilitate the receiving health IT system's interpretation and use of the EHI to the extent reasonably practicable using the developer's existing technology.

This criterion provides developers with the ability to create innovative export capabilities according to their systems and data practices. We do not propose that the export must be executed according to any particular standard, but propose to require that the export must be accompanied by the data format, including its structure and syntax, to facilitate interpretation of the EHI therein. Overall, this new criterion is intended to provide patients and health IT users, including providers, a means to efficiently export the entire electronic health record for a single patient or all patients in a computable, electronic format.

[1] *https://ecqi.healthit.gov/qrda-quality-reporting-document-architecture.*

e. Application Programming Interfaces (APIs)

We propose to adopt a new API criterion in § 170.315(g)(10), which would replace the ''application access—data category request'' certification criterion (§ 170.315(g)(8)) and become part of the 2015 Edition Base EHR definition. This new ''standardized API for patient and population services'' certification criterion would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards[2] and several implementation specifications. The new criterion would focus on supporting two types of API-enabled services: (1) Services for which a single patient's data is the focus and (2) services for which multiple patients' data are the focus.

f. Privacy and Security Transparency Attestations

We propose to adopt two new privacy and security transparency attestation certification criteria, which would identify whether certified health IT supports encrypting authentication credentials and/or multi-factor authentication. In order to be issued a certification, we propose to require that a Health IT Module developer attest to whether the Health IT Module encrypts authentication credentials and whether the Health IT Module supports multi-factor authentication. These criteria are not expected to place additional burden on health IT developers since they do not require net new development or implementation to take place in order to be met. However, certification to these proposed criteria would provide increased transparency and potentially motivate health IT developers to encrypt authentication credentials and support multi- factor authentication, which could help prevent exposure to unauthorized persons/entities.

g. Data Segmentation for Privacy and Consent Management

In the 2015 Edition, we adopted two ''data segmentation for privacy'' (DS4P) certification criteria, one for creating a summary record according to the DS4P standard and one for receiving a summary record according to the DS4P standard. Certification to the 2015 Edition DS4P criteria focus on data segmentation only at the document level. As noted in the 2015 Edition final rule (80 FR 62646)—and to our knowledge still an accurate assessment—certification to these criteria is currently not required to meet the Certified EHR Technology definition

[2] *https://www.hl7.org/fhir/overview.html.*

(CEHRT) or required by any other HHS program. Since the 2015 Edition final rule, the health care industry has engaged in additional field testing and implementation of the DS4P standard. In addition, stakeholders shared with ONC—through public forums, listening sessions, and correspondence—that focusing certification on segmentation to only the document level does not permit providers the flexibility to address more granular segmentation needs. Therefore, we propose to remove the current 2015 Edition DS4P criteria. We propose to replace these two criteria with three new 2015 Edition ''DS4P'' certification criteria (two for C–CDA and one for a FHIR-based API) that would support a more granular approach to privacy tagging data consent management for health information exchange supported by either the C–CDA- or FHIR-based exchange standards.

3. Modifications to the ONC Health IT Certification Program

We propose to make corrections to the 2015 Edition privacy and security certification framework (80 FR 62705) and relevant regulatory provisions. These corrections have already been incorporated in the relevant Certification Companion Guides (CCGs).

We propose new and revised principles of proper conduct (PoPC) for ONC-Authorized Certification Bodies (ONC–ACBs). We propose to clarify that the records retention provision includes the ''life of the edition'' as well as after the retirement of an edition related to the certification of Complete EHRs and Health IT Modules. We also propose to revise the PoPC in § 170.523(h) to clarify the basis for certification, including to permit a certification decision to be based on an evaluation conducted by the ONC–ACB for Health IT Modules' compliance with certification criteria by use of conformity methods approved by the National Coordinator for Health Information Technology (National Coordinator). We also propose to update § 170.523(h) to require ONC–ACBs to accept test results from any ONC–ATL that is in good standing under the Program and is compliant with its ISO 17025 accreditation requirements. We believe these proposed new and revised PoPCs would provide necessary clarifications for ONC–ACBs and would promote stability among the ONC–ACBs. We also propose to update § 170.523(k) to broaden the requirements beyond just the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (now renamed the Promoting Interoperability Programs) and provide other necessary clarifications.

We propose to revise a PoPC for ONC–ATLs. We propose to clarify that the records retention provision includes the ''life of the edition'' as well as after the retirement of an edition related to the certification of Complete EHRs and Health IT Modules.

4. Health IT for the Care Continuum

Section 4001(b) of the Cures Act includes two provisions related to supporting health IT across the care continuum. The first instructs the National Coordinator to encourage, keep or recognize through existing authorities, the voluntary certification of health IT for use in medical specialties and sites of service where more technological advancement or integration is needed. The second outlines a provision related to the voluntary certification of health IT for use by pediatric health providers to support the health care of children. These provisions align closely with ONC's core purpose to promote interoperability to support care coordination, patient engagement, and health care quality improvement initiatives. Advancing health IT that promotes and supports patient care when and where it is needed continues to be a primary goal of the Program. This means health IT should support patient populations, specialized care, transitions of care, and practice settings across the care continuum.

ONC has explored how we might work with the health IT industry and with specialty organizations to collaboratively develop and promote health IT that supports medical specialties and sites of service. Over time, ONC has taken steps to make the Program modular, more open and accessible to different types of health IT, and able to advance functionality that is generally applicable to a variety of care and practice settings. Specific to the provisions in the Cures Act to support providers of health care for children, we considered a wide range of factors. These include: The evolution of health IT across the care continuum, the costs and benefits associated with health IT, the potential regulatory burden and compliance timelines, and the need to help advance health IT that benefits multiple medical specialties and sites of service involved in the care of children. In consideration of these factors, and to advance implementation of Sections 4001(b) of the Cures Act specific to pediatric care, we held a listening session where stakeholders could share their clinical knowledge and technical expertise in pediatric care and pediatric sites of service. Through the information learned at this listening session and our analysis of the health IT landscape for pediatric settings, we have identified existing 2015 Edition criteria, as well as new and revised 2015 Edition criteria proposed in this rule, that we believe could benefit providers of pediatric care and pediatric settings. In this proposed rule, we seek comment on our analysis and the correlated certification criteria that we believe would support the health care of children.

We also recognize the significance of the opioid epidemic confronting our nation and the importance of helping to support the health IT needs of health care providers committed to preventing inappropriate access to prescription opioids and to providing safe, appropriate treatment. We believe health IT offers promising strategies to help assist medical specialties and sites of services impacted by the opioid epidemic. Therefore, we request public comment on how our existing Program requirements and the proposals in this rulemaking may support use cases related to Opioid Use Disorder (OUD) prevention and treatment and if there are additional areas that ONC should consider for effective implementation of health IT to help address OUD prevention and treatment.

5. Conditions and Maintenance of Certification

We propose to establish certain Conditions and Maintenance of Certification requirements for health IT developers based on the conditions and maintenance of certification requirements outlined in section 4002 of the Cures Act. We propose an approach whereby the Conditions and Maintenance of Certification express both initial requirements for health IT developers and their certified Health IT Module(s) as well as ongoing requirements that must be met by both health IT developers and their certified Health IT Module(s) under the Program. In this regard, we propose to implement the Cures Act Conditions of Certification with further specificity as it applies to the Program and propose to implement any accompanying Maintenance of Certification requirements as standalone requirements to ensure that not only are the Conditions of Certification met, but that they are continually being met through the Maintenance of Certification requirements. For ease of reference and to distinguish from other conditions, we propose to capitalize ''Conditions of Certification'' and ''Maintenance of Certification'' when referring to Conditions and Maintenance

of Certification requirements established under the Cures Act.

Information Blocking

The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, not take any action that constitutes information blocking as defined in section 3022(a) of the Public Health Service Act (PHSA). We propose to establish this information blocking Condition of Certification in § 170.401. The Condition of Certification would prohibit any health IT developer under the Program from taking any action that constitutes information blocking as defined by section 3022(a) of the PHSA and proposed in § 171.103.

Assurances

Section 3001(c)(5)(D)(ii) of the Cures Act requires that a health IT developer, as a Condition of Certification under the Program, provide assurances to the Secretary that, unless for legitimate purposes specified by the Secretary, the developer will not take any action that constitutes information blocking as defined in section 3022(a) of the PHSA, or any other action that may inhibit the appropriate exchange, access, and use of EHI. We propose to implement this provision through several Conditions of Certification and accompanying Maintenance requirements, which are set forth in proposed § 170.402. We also propose to establish more specific Conditions and Maintenance of Certification requirements to provide assurances that a health IT developer does not take any other action that may inhibit the appropriate exchange, access, and use of EHI. These proposed requirements serve to provide further clarity under the Program as to how health IT developers can provide such broad assurances with more specific actions.

Communications

As a Condition and Maintenance of Certification under the Program, the Cures Act requires that health IT developers do not prohibit or restrict communications about certain aspects of the performance of health IT and the developers' related business practices. We propose that developers will be permitted to impose certain kinds of limited prohibitions and restrictions that we believe strike a reasonable balance between the need to promote open communication about health IT and related developer business practices and the need to protect the legitimate interests of health IT developers and other entities. However, certain narrowly-defined types of communications—such as communications required by law, made to a government agency, or made to a defined category of safety organization—would receive ''unqualified protection,'' meaning that developers would be absolutely prohibited from imposing any prohibitions or restrictions on such protected communications.

We propose that to maintain compliance with this Condition of Certification, a health IT developer must not impose or enforce any contractual requirement or legal right that contravenes this Condition of Certification. Furthermore, we propose that if a health IT developer has contracts/agreements in existence that contravene this condition, the developer must notify all affected customers or other persons or entities that the prohibition or restriction will not be enforced by the health IT developer. Going forward, health IT developers would be required to amend their contracts/agreements to remove or make void the provisions that contravene this Condition of Certification within a reasonable period of time, but not later than two years from the effective date of a subsequent final rule for this proposed rule.

Application Programming Interfaces (APIs)

The Cures Act's API Condition of Certification includes several key phrases (including, for example, ''without special effort'') and requirements for health IT developers that indicate the Cures Act's focus on the technical requirements as well as the actions and practices of health IT developers in implementing the certified API. In section VII.B.4 of the preamble, we outline our proposals to implement the Cures Act's API Condition of Certification. These proposals include new standards, new implementation specifications, a new certification criterion, as well as detailed Conditions and Maintenance of Certification requirements.

Real World Testing

The Cures Act adds a new Condition and Maintenance of Certification requirement that health IT developers successfully test the real world use of the technology for interoperability in the type of setting in which such technology would be marketed. In this proposed rule, we outline what successful ''real world testing'' means for the purpose of this Condition of Certification, as well as proposed Maintenance requirements—including standards updates for widespread and continued interoperability.

We propose to limit the applicability of this Condition of Certification to health IT developers with Health IT Modules certified to one or more 2015 Edition certification criteria focused on interoperability and data exchange specified in section VII.B.5. We propose Maintenance of Certification requirements that would require health IT developers to submit publicly available annual real world testing plans as well as annual real world testing results for certified health IT products focused on interoperability. We also propose a Maintenance of Certification flexibility we have named the Standards Version Advancement Process, under which health IT developers with health IT certified to the criteria specified for interoperability and data exchange would have the option to update their health IT to a more advanced version(s) of the standard(s) or implementation specification(s) included in the criteria once such versions are approved by the National Coordinator through the Standards Version Advancement Process for use in health IT certified under the Program. Similarly, we propose that health IT developers presenting new health IT for certification to one of the criteria specified in Section VII.B.5 would have the option to certify to a National Coordinator-approved more advanced version of the adopted standards or implementation specifications included in the criteria. We propose that health IT developers voluntarily opting to avail themselves of the Standards Version Advancement Process must address their planned and actual timelines for implementation and rollout of standards updates in their annual real world testing plans and real world testing results submissions. We also propose that health IT developers of products with existing certifications who plan to avail themselves of the Standards Version Advancement Process flexibility notify both their ONC–ACB and their affected customers of their intention and plans to update their certified health IT and its anticipated impact on their existing certified health IT and customers, specifically including but not limited to whether, and if so for how long, the health IT developer intends to continue to support the certificate for the health IT certified to the prior version of the standard.

We propose a new PoPC for ONC–ACBs that would require ONC–ACBs to review and confirm that applicable health IT developers submit real world testing plans and real world results in accordance with our proposals. Once

completeness is confirmed, ONC–ACBs would upload the plans and results via hyperlinks to the Certified Health IT Product List (CHPL). We propose to revise the PoPC in § 170.523(m) to require ONC–ACBs to collect, no less than quarterly, all updates successfully made to standards in certified health IT pursuant to the developers having voluntarily opted to avail themselves of the Standards Version Advancement Process flexibility under the real world testing Condition of Certification. We propose in § 170.523(t), a new PoPC for ONC–ACBs requiring them to ensure that developers seeking to take advantage of the Standards Version Advancement Process flexibility in § 170.405(b)(5) comply with the applicable requirements.

Attestations

The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, provide to the Secretary an attestation to all the Conditions of Certification specified in the Cures Act, except for the ''EHR reporting criteria submission'' Condition of Certification. We propose to implement the Cures Act ''attestations'' Condition of Certification in § 170.406. Health IT developers would attest twice a year to compliance with the Conditions and Maintenance of Certification requirements (except for the EHR reporting criteria requirement, which would be metrics reporting requirements separately implemented through a future rulemaking). The 6-month attestation period we propose in § 170.406(b)(2) would properly balance the need to support appropriate enforcement with the attestation burden placed on health IT developers. In this regard, the proposed rule includes provisions to make the process as simple and efficient for health IT developers as possible (*e.g.,* 14-day grace period, web-based form submissions, and attestation alert reminders).

We propose that attestations would be submitted to ONC–ACBs on behalf of ONC and the Secretary. We propose a new PoPC in § 170.523(q) that an ONC–ACB must review and submit the health IT developers' attestations to ONC. ONC would then make the attestations publicly available through the CHPL.

EHR Reporting Criteria Submission

The Cures Act specifies that health IT developers be required, as a Condition and Maintenance of Certification under the Program, to submit reporting criteria on certified health IT in accordance with the EHR reporting program established under section 3009A of the PHSA, as added by the Cures Act. We have not yet established an EHR reporting program. Once ONC establishes such program, we will undertake rulemaking to propose and implement the associated Condition and Maintenance of Certification requirement(s) for health IT developers.

Enforcement

Section 4002 of the Cures Act adds Program requirements aimed at addressing health IT developer actions and business practices through the Conditions and Maintenance of Certification requirements, which expands the current focus of the Program requirements beyond the certified health IT itself. Equally important, section 4002 also provides that the Secretary of HHS may encourage compliance with the Conditions and Maintenance of Certification requirements and take action to discourage noncompliance. We, therefore, propose a general enforcement approach to encourage consistent compliance with the requirements. The proposed rule outlines a corrective action process for ONC to review potential or known instances where a Condition or Maintenance of Certification requirement has not been or is not being met by a health IT developer under the Program. We propose, with minor modifications, to utilize the processes previously established for ONC direct review of certified health IT and codified in §§ 170.580 and 170.581 for the enforcement of the Conditions and Maintenance of Certification requirements. Where noncompliance is identified, our first priority would be to work with the health IT developer to remedy the matter through a corrective action process. However, we propose that, under certain circumstances, ONC may ban a health IT developer from the Program or terminate the certification of one or more of its Health IT Modules.

6. Information Blocking

Section 4004 of the Cures Act added section 3022 of the PHSA (42 U.S.C. 300jj–52, ''the information blocking provision''), which defines conduct by health care providers, and health IT developers of certified health IT, exchanges, and networks that constitutes information blocking. Section 3022(a)(1) of the PHSA defines information blocking in broad terms, while section 3022(a)(3) authorizes and charges the Secretary to identify reasonable and necessary activities that do not constitute information blocking (section 3022(a)(3) of the PHSA).

We identify several reasonable and necessary activities as exceptions to the information blocking definition, each of which we propose would not constitute information blocking for purposes of section 3022(a)(1) of the PHSA. The exceptions would extend to certain activities that interfere with the access, exchange, or use of EHI but that may be reasonable and necessary if certain conditions are met.

In developing the proposed exceptions, we were guided by three overarching policy considerations. First, the exceptions would be limited to certain activities that clearly advance the aims of the information blocking provision; promoting public confidence in health IT infrastructure by supporting the privacy and security of EHI, and protecting patient safety; and promoting competition and innovation in health IT and its use to provide health care services to consumers. Second, each exception is intended to address a significant risk that regulated individuals and entities (*i.e.,* health care providers, health IT developers of certified health IT, health information networks, and health information exchanges) will not engage in these reasonable and necessary activities because of potential uncertainty regarding whether they would be considered information blocking. Third, and last, each exception is intended to be tailored, through appropriate conditions, so that it is limited to the reasonable and necessary activities that it is designed to exempt.

The seven proposed exceptions are set forth in section VIII.D below. The first three exceptions, set forth in VIII.D.1–D.3 address activities that are reasonable and necessary to promote public confidence in the use of health IT and the exchange of EHI. These exceptions are intended to protect patient safety; promote the privacy of EHI; and promote the security of EHI. The next three exceptions, set forth in VIII.D.4–D.6, address activities that are reasonable and necessary to promote competition and consumer welfare. These exceptions would allow for the recovery of costs reasonably incurred; excuse an actor from responding to requests that are infeasible; and permit the licensing of interoperability elements on reasonable and non-discriminatory terms. The last exception, set forth in VIII.D.7, addresses activities that are reasonable and necessary to promote the performance of health IT. This proposed exception recognizes that actors may make health IT temporarily unavailable for maintenance or improvements that

benefit the overall performance and usability of health IT.

To qualify for any of these exceptions, we propose that an individual or entity would, for each relevant practice and at all relevant times, have to satisfy all of the applicable conditions of the exception. Additionally, we propose (in section VIII.C of this preamble) to define or interpret terms that are present in section 3022 of the PHSA (such as the types of individuals and entities covered by the information blocking provision). We also propose certain new terms and definitions that are necessary to implement the information blocking provisions. We propose to codify the proposed exceptions and other information blocking proposals in a new part of title 45 of the Code of Federal Regulations, part 171.

C. Costs and Benefits

Executive Orders 12866 on Regulatory Planning and Review (September 30, 1993) and 13563 on Improving Regulation and Regulatory Review (February 2, 2011) direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). OMB has determined that this proposed rule is an economically significant rule as the potential costs associated with this proposed rule could be greater than $100 million per year. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of this proposed rule.

We have estimated the potential monetary costs and benefits of this proposed rule for health IT developers, health care providers, patients, ONC–ACBs, ONC–ATLs, and the federal government (*i.e.,* ONC), and have broken those costs and benefits out into the following categories: (1) Deregulatory actions (no associated costs); (2) updates to the updates to the 2015 Edition health IT certification criteria; (3) Conditions and Maintenance of Certification for a health IT developer; (4) oversight for the Conditions and Maintenance of Certification; and (5) information blocking.

We note that we have rounded all estimates to the nearest dollar and all estimates are expressed in 2016 dollars as it is the most recent data available to address all cost and benefit estimates consistently. We also note that we did not have adequate data to quantify some of the costs and benefits within this RIA. In those situations, we have described the qualitative costs and benefits of our proposals; however, such qualitative costs and benefits have not been accounted for in the monetary cost and benefit totals below.

We estimate that the total annual cost for this proposed rule for the first year after it is finalized (including one-time costs), based on the cost estimates outlined above and throughout this RIA, would, on average, range from $365 million to $919 million with an average annual cost of $642 million. We estimate that the total perpetual cost for this proposed rule (starting in year two), based on the cost estimates outlined above, would, on average, range from $228 million to $452 million with an average annual cost of $340 million.

We estimate the total annual benefit for this proposed rule would range from $3.08 billion to $9.15 billion with an average annual benefit of $6.1 billion.

We estimate the total annual net benefit for this proposed rule for the first year after it is finalized (including one-time costs), based on the cost and benefit estimates outlined above, would range from $2.7 billion to $8.2 billion with an average net benefit of $5.5 billion. We estimate the total perpetual annual net benefit for this proposed rule (starting in year two), based on the cost-benefit estimates outlined above, would range from $2.9 billion to $8.7 billion with an average net benefit of $5.8 billion.

II. Background

A. Statutory Basis

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created ''Title XXX—Health Information Technology and Quality'' (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health IT and electronic health information (EHI) exchange.

The Cures Act was enacted on December 13, 2016, to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes. The Cures Act, through Title IV—Delivery, amended the HITECH Act (Title XIII of Division A of Pub. L. 111–5) by modifying or adding certain provisions to the PHSA relating to health IT.

1. Standards, Implementation Specifications, and Certification Criteria

The HITECH Act established two new federal advisory committees, the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC). Each was responsible for advising the National Coordinator for Health Information Technology (National Coordinator) on different aspects of standards, implementation specifications, and certification criteria.

Section 3002 of the Cures Act amended the PHSA by replacing the HITPC and HITSC with one committee, the Health Information Technology Advisory Committee (HIT Advisory Committee or HITAC). Section 3002(a) establishes that the HITAC shall advise and recommend to the National Coordinator on different aspects of standards, implementation specifications, and certification criteria, relating to the implementation of a health IT infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. Further described in section 3002(b)(1)(A) of the PHSA, this includes providing to the National Coordinator recommendations on a policy framework to advance interoperable health IT infrastructure, updating recommendations to the policy framework, and making new recommendations, as appropriate. Section 3002(b)(2)(A) identifies that in general, the HITAC shall recommend to the National Coordinator for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Like the process previously required of the former HITPC and HITSC, the HITAC will develop a schedule for the assessment of policy recommendations for the Secretary to publish in the **Federal Register**.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1), the Secretary is required, in consultation with representatives of other relevant federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) and subsequently

determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA titled, Subsequent Standards Activity, provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the HITAC. We consider this provision in the broader context of the HITECH Act and Cures Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria.

2. Health IT Certification Program(s)

Under the HITECH Act, section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of health IT. Specifically, section 3001(c)(5)(A) specifies that the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology (NIST), shall keep or recognize a program or programs for the voluntary certification of health IT that is in compliance with applicable certification criteria adopted under this subtitle (*i.e.,* certification criteria adopted by the Secretary under section 3004 of the PHSA). The certification program(s) must also include, as appropriate, testing of the technology in accordance with section 13201(b) of the HITECH Act. Overall, section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of NIST shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. The HITECH Act also indicates that the development of this conformance testing infrastructure may include a program to accredit independent, non-federal laboratories to perform testing.

Section 3001(c)(5) of the PHSA was amended by the Cures Act, which instructs the National Coordinator to encourage, keep, or recognize, through existing authorities, the voluntary certification of health IT under the Program for use in medical specialties and sites of service for which no such technology is available or where more technological advancement or integration is needed. Section 3001(c)(5)(C)(iii) identifies that the Secretary, in consultation with relevant stakeholders, shall make recommendations for the voluntary certification of health IT for use by pediatric health providers to support the care of children, as well as adopt certification criteria under section 3004 to support the voluntary certification of health IT for use by pediatric health providers. The Cures Act further amended section 3001(c)(5) of the PHSA by adding section 3001(c)(5)(D), which provides the Secretary with the authority, through notice and comment rulemaking, to require conditions and maintenance of certification requirements for the Program.

B. Regulatory History

The Secretary issued an interim final rule with request for comments (75 FR 2014, Jan. 13, 2010), which adopted an initial set of standards, implementation specifications, and certification criteria. On March 10, 2010, ONC published a proposed rule (75 FR 11328) that proposed both a temporary and permanent certification program for the purposes of testing and certifying health IT. A final rule establishing the temporary certification program was published on June 24, 2010 (75 FR 36158) and a final rule establishing the permanent certification program was published on January 7, 2011 (76 FR 1262). ONC issued multiple rulemakings since these initial rulemaking to update standards, implementation specifications, and certification criteria and the certification program, a history of which can be found in the final rule titled, ''2015 Edition Health Information (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' (Oct. 16, 2015, 80 FR 62602) (''2015 Edition final rule''). A correction notice was published for the 2015 Edition final rule on December 11, 2015 (80 FR 76868) to correct preamble and regulatory text errors and clarify requirements of the Common Clinical Data Set (CCDS), the 2015 Edition privacy and security certification framework, and the mandatory disclosures for health IT developers.

The 2015 Edition final rule established a new edition of certification criteria (''2015 Edition health IT certification criteria'' or ''2015 Edition'') and a new 2015 Edition Base EHR definition. The 2015 Edition established the capabilities and specified the related standards and implementation specifications that CEHRT would need to include to, at a minimum, support the achievement of ''meaningful use'' by eligible clinicians, eligible hospitals, and critical access hospitals under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) (now referred to as the Promoting Interoperability Programs) [3] when the 2015 Edition is required for use under these and other programs referencing the CEHRT definition. The 2015 Edition final rule also made changes to the Program. The final rule adopted a proposal to change the Program's name to the ''ONC Health IT Certification Program'' from the ONC *HIT* Certification Program, modified the Program to make it more accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond the ambulatory and inpatient settings, and adopted new and revised Principles of Proper Conduct (PoPC) for ONC–ACBs.

After issuing a proposed rule on March 2, 2016 (81 FR 11056), ONC published a final rule titled, ''ONC Health IT Certification Program: Enhanced Oversight and Accountability'' (81 FR 72404) (''EOA final rule'') on October 19, 2016. The final rule finalized modifications and new requirements under the Program, including provisions related to ONC's role in the Program. The final rule created a regulatory framework for ONC's direct review of health IT certified under the Program, including, when necessary, requiring the correction of non-conformities found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. The final rule also sets forth processes for ONC to authorize and oversee accredited testing laboratories under the Program. In addition, it includes provisions for expanded public availability of certified health IT surveillance results.

III. Deregulatory Actions for Previous Rulemakings

A. Background

1. History of Burden Reduction and Flexibility

Since the inception of the ONC Health IT Certification Program (Program), we have aimed to implement and administer the Program in the least burdensome manner that supports our policy goals. Throughout the years, we

[3] *https://www.federalregister.gov/d/2018-16766/p-4.*

have worked to improve the Program with a focus on ways to reduce burden, offer flexibility to both developers and providers, and support innovation. This approach has been consistent with the principles of Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), which instructs agencies to ''determine whether any [agency] regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.'' To that end, we have historically, where feasible and appropriate, taken measures to reduce burden within the Program and make the Program more effective, flexible, and streamlined.

For example, in the 2014 Edition final rule (77 FR 54164), we revised the certified electronic health record technology (CEHRT) definition to provide flexibility and create regulatory efficiencies by narrowing required functionality to a core set of capabilities (*i.e.,* the Base EHR definition) plus the additional capabilities each eligible clinician, eligible hospital, and critical access hospital needed to successfully achieve the applicable objective and measures under the EHR Incentive Programs (now referred to as the Promoting Interoperability Programs). ONC has also supported more efficient testing and certification methods and reduced regulatory burden through the adoption of a gap certification policy. As explained in the 2014 Edition final rule (77 FR 54254) and the 2015 Edition final rule (80 FR 62681), where applicable, gap certification allows for the use of a previously certified health IT product's test results to certification criteria identified as unchanged. Developers have been able to use gap certification for the more efficient certification of their health IT when updating from the 2011 Edition to the 2014 Edition and from the 2014 Edition to the 2015 Edition.

ONC introduced further means to reduce regulatory burden, increase regulatory flexibility, and promote innovation in the 2014 Edition Release 2 final rule (79 FR 54430). The 2014 Edition Release 2 final rule established a set of optional 2014 Edition certification criteria that provided flexibility and alternative certification pathways for health IT developers and providers based on their specific circumstances. The 2014 Edition Release 2 final rule also simplified the Program by discontinuing the use of the ''Complete EHR'' certification concept beginning with the 2015 Edition (79 FR 54443).

In the 2015 Edition final rule, we did not ''carry forward'' certain 2014 Edition certification criteria into the 2015 Edition, such as the ''image results,'' ''patient list creation,'' and ''electronic medication administration record'' criteria. We determined that these criteria did not advance functionality or support interoperability (80 FR 62682–84). We also did not require all health IT to be certified to the ''meaningful use measurement'' certification criteria for ''automated numerator recording'' and ''automated measure calculation'' (80 FR 62605), which had been previously required for the 2014 Edition. Based on stakeholder feedback and Program administration observations, we also permitted testing efficiencies for the 2015 Edition ''automated numerator recording'' and ''automated measure calculation'' criteria by removing the live demonstration requirement of recording data and generating reports. Health IT developers may now self-test their Health IT Modules(s) and submit the resulting reports to the ONC-Authorized Testing Laboratory (ONC–ATL) to verify compliance with the criterion.[4] In order to further reduce burden for health IT developers, we adopted a simpler, straight-forward approach to privacy and security certification requirements, which clarified which requirements are applicable to each criterion within the regulatory functional areas (80 FR 62605).

2. Executive Orders 13771 and 13777

On January 30, 2017, the President issued Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs, which requires agencies to identify deregulatory actions. This order was followed by Executive Order 13777, titled ''Enforcing the Regulatory Reform Agenda'' (February 24, 2017). Executive Order 13777 provides further direction on implementing regulatory reform by identifying a process by which agencies must review and evaluate existing regulations and make recommendations for repeal or simplification.

In order to implement these regulatory reform initiatives and policies, over the past year ONC reviewed and evaluated existing regulations. During our review, we sought to identify ways to further reduce administrative burden, to implement deregulatory actions through guidance, and to propose potential new deregulatory actions in this proposed rule that will reduce burden for health IT developer, providers, and other stakeholders.

On August 21, 2017, ONC issued *Relied Upon Software Program Guidance.*[5] Health IT developers are permitted to use ''relied upon software'' (76 FR 1276) to demonstrate compliance with certification criteria adopted at 45 CFR part 170, subpart C. Historically, in cases where a Health IT Module is paired with multiple ''relied upon software'' products for the same capability, health IT developers were required to demonstrate compliance for the same certification criterion with each of those ''relied upon software'' products in order for the products to be listed on the Certified Health IT Product List (CHPL). With the issued guidance, health IT developers may now demonstrate compliance with only one ''relied upon software'' product for a criterion/capability. Once the health IT developer demonstrates compliance with a minimum of one ''relied upon software'' product, the developer can have multiple, additional ''relied upon software'' products for the same criterion/capability listed on the CHPL (*https://chpl.healthit.gov/*). This approach reduces burden for health IT developers, ONC–ATLs, and ONC-Authorized Certification Bodies (ONC–ACBs).

On September 21, 2017, ONC reduced the overall burden for testing health IT to the 2015 Edition.[6] ONC reviewed the 2015 Edition test procedures, which identify minimum testing requirements ONC–ATLs must evaluate during testing. ONC changed 30 of the 2015 Edition test procedures to attestation only (*i.e.,* a ''yes'' self-declaration by the health IT developer that their product has capabilities conformant with those specified in the associated certification criterion/criteria).[7] This deregulatory action reduced burden and costs program-wide, while still maintaining the Program's high level of integrity and assurances. Health IT developers now have reduced preparation and testing costs for testing to these criteria. Specifically, the cost savings for health IT developers have been estimated between $8.34 and $9.26 million. ONC–ATLs also benefit by having more time and resources to focus on tool-based

[4] *https://www.healthit.gov/test-method/automated-numerator-recording* and *https://www.healthit.gov/test-method/automated-measure-calculation.*

[5] *https://www.healthit.gov/sites/default/files/relieduponsoftwareguidance.pdf.*

[6] *https://www.healthit.gov/buzz-blog/healthit-certification/certification-program-updates-support-efficiency-reduce-burden/.*

[7] *https://www.healthit.gov/sites/default/files/policy/selfdeclarationapproachprogramguidance17-04.pdf.*

testing (for interoperability-oriented criteria) and being responsive to any retesting requirements that may arise from ONC–ACB surveillance activities. Furthermore, providers and users of certified health IT do not lose confidence in the Program because this burden reduction effort in no way alters the expectations of conformance and responsibilities of Program participants. Health IT developers are still required to meet certification criteria requirements and maintain their products' conformance to the full scope of the associated criteria, including when implemented in the field and in production use. Similarly, ONC and ONC–ACBs continue to conduct surveillance activities and respond to end-user complaints.

B. Proposed Deregulatory Actions

We propose six deregulatory actions below. We welcome comments on these potential deregulatory actions and any other potential deregulatory actions we should consider. We also refer readers to section XIV (Regulatory Impact Analysis) of this proposed rule for a discussion of the estimated cost savings from these proposed deregulatory actions.

1. Removal of Randomized Surveillance Requirements

ONC–ACBs are required to conduct surveillance of certified health IT under the Program to ensure that health IT continues to conform and function as required by the full scope of the certification requirements. Surveillance is categorized as either reactive surveillance (for example, complaint-based surveillance) or randomized surveillance, which, by regulation, requires ONC–ACBs to proactively surveil 2% of the certificates they issue annually. On September 21, 2017, we exercised enforcement discretion with respect to the implementation of randomized surveillance by ONC–ACBs.[8] Consistent with this exercise of enforcement discretion, we now propose to eliminate certain regulatory randomized surveillance requirements.

We propose to revise § 170.556(c) by changing the requirement that ONC–ACBs *must* conduct in-the-field, randomized surveillance to specify that ONC–ACBs *may* conduct in-the- field, randomized surveillance. We further propose to remove § 170.556(c)(2), which specifies that ONC–ACBs must conduct randomized surveillance for a minimum of 2% of certified health IT products per year. We also propose to remove the requirements in § 170.556(c)(5) regarding the exclusion and exhaustion of selected locations for randomized surveillance. Additionally, we propose to remove the requirements in § 170.556(c)(6) regarding the consecutive selection of certified health IT for randomized surveillance. Without these regulatory requirements, ONC–ACBs would still be required to perform reactive surveillance, and would be permitted to conduct randomized surveillance of their own accord, using the methodology identified by ONC with respect to scope (§ 170.556(c)(1)), selection method (§ 170.556(c)(3)), and the number and types of locations for in-the-field surveillance (§ 170.556(c)(4)).

Stakeholders have expressed concern that the benefits of in-the-field, randomized surveillance may not outweigh the time commitment required by providers, particularly if no non-conformities are found. In general, providers have expressed that reactive surveillance (*e.g.,* surveillance based on user complaints) is a more logical and economical approach to surveillance. The removal of randomized surveillance requirements would also give ONC–ACBs the flexibility and time to focus on other priorities, such as the certification of health IT to the 2015 Edition. Therefore, as discussed above, we propose to eliminate certain regulatory randomized surveillance requirements.

2. Removal of the 2014 Edition From the Code of Federal Regulations

We propose to remove the 2014 Edition from the Code of Federal Regulations (CFR). The 2014 Edition was the result of rulemaking completed in 2012 and includes standards and functionality that are now significantly outmoded. Removal of the 2014 Edition would make the 2015 Edition the baseline for health IT certification. The 2015 Edition, including the additional certification criteria, standards, and requirements proposed in this proposed rule, better enables interoperability and the access, exchange, and use of electronic health information. Adoption and implementation of the 2015 Edition, including the proposals in this proposed rule, would also lead to the benefits outlined in the 2015 Edition final rule (80 FR 62602–62603, 62605–62606, 62740) and in this proposed rule (*see, for example,* the Executive Summary and the ''Assurances,'' ''API'', and ''Real World Testing'' Conditions and Maintenance of Certification sections). Equally important, adoption and implementation of the 2015 Edition by providers would lead to the estimated costs savings in this proposed rule through improved interoperability supporting the access, exchange, and use of electronic health information.

Removal of the 2014 Edition would eliminate inconsistencies and costs caused by health IT certification and implementation of two different editions with different functionalities and versions of standards. Patient care could improve through the reduced risk of error that comes with the health care system's consistent implementation and use of health IT certified to the 2015 Edition. Innovation could also improve with health IT developers (including third-party software developers) developing to only one set of newer standards and implementation specifications, which would be more predictable and less costly.

Removal of the 2014 Edition would also reduce regulatory burden by no longer requiring the maintenance and support of the 2014 Edition. Maintaining compliance with only the 2015 Edition would reduce the cost and burden for health IT developers, ONC–ACBs, and ONC–ATLs because they would no longer have to support two increasingly distinct sets of requirements as is the case now with certification to both the 2014 and 2015 Editions. More specifically, health IT developers would not have to support two maintenance infrastructures and updating for their customers; nor would ONC–ATLs and ONC–ACBs have to support testing, certification, and surveillance for two separate editions of certified health IT.

As referenced by the HHS Office of Inspector General (OIG) and Centers for Medicare & Medicaid Services (CMS) in their rulemakings regarding donations of EHR items and services, we committed to retiring certification criteria editions that are no longer applicable.[9] We first did this with the removal of the 2011 Edition (79 FR 54447). Accordingly, our proposal to remove the outdated 2014 Edition for the reasons discussed above would also streamline Program compliance requirements and ensure there is no regulatory confusion between ONC's rules and other HHS rules.

To implement the removal of the 2014 Edition from the CFR, we propose to remove the 2014 Edition certification

[8] *https://www.healthit.gov/sites/default/files/ONC_Enforcement_Discretion_Randomized_Surveillance_8-30-17.pdf.*

[9] CMS final rule ''Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships: Exception for Certain Electronic Health Records Arrangements'' (*78 FR 78751*).OIG final rule ''Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute'' (*78 FR 79202*).

criteria (§ 170.314) and related standards, terms, and requirements from the CFR. In regard to terms, we propose to retire the 2014 Edition-related definitions found in § 170.102, including the ''2014 Edition Base EHR,'' ''2014 Edition EHR certification criteria,'' and ''Complete EHR, 2014 Edition.'' As explained in the 2015 Edition final rule (80 FR 62719), the ability to maintain Complete EHR certification is only permitted with health IT certified to the 2014 Edition certification criteria. Because this concept was discontinued for the 2015 Edition, we propose to remove § 170.545 and any references to Complete EHR from the regulation text in conjunction with the removal of the 2014 Edition. We also propose to remove references to the 2014 Edition from the Common Clinical Data Set (CCDS) definition. However, as discussed later in section IV.B.1 (''United States Core Data for Interoperability'') of this proposed rule, we propose to remove the CCDS definition from the CFR and effectively replace it with a new government-unique standard, the United States Core Data for Interoperability (USCDI), proposing to adopt Version 1 (v1) in § 170.213. The new standard would be applicable to certain 2015 Edition certification criteria that currently reference the CCDS, subject to any of these criteria being removed through this rulemaking).

We propose to remove the standards and implementation specifications found in §§ 170.200, 170.202, 170.204, 170.205, 170.207, 170.210, and 170.299 that are only referenced in the 2014 Edition certification criteria. Adopted standards that are also referenced in the 2015 Edition would remain. We propose to remove requirements in § 170.550(f) and any other requirements in subpart E, §§ 170.500 through 170.599, which are specific to the 2014 Edition and do not apply to the 2015 Edition.

In order to avoid regulatory conflicts, we are taking into consideration the final rule released by CMS on November 2, 2017, which makes payment and policy changes to the second year of the Quality Payment Program (QPP). The CMS's final rule, titled ''Medicare Program; CY 2018 Updates to the Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year'' (82 FR 53568), permits eligible clinicians to use health IT certified to either the 2014 or 2015 Edition certification criteria, or a combination of the two for the CY 2018 performance period. The QPP final rule also states that the 2015 Edition will be the sole edition permitted to meet the CEHRT definition starting with the CY 2019 program year.

Therefore, we propose that the effective date of removal of the 2014 Edition certification criteria and related standards, terms, and requirements from the CFR would be the effective date of a subsequent final rule for this proposed rule, which we expect will be issued in the latter half of 2019. We note that we will continue to support Medicare and Medicaid program attestations by maintaining an archive on the CHPL allowing the public to access historic information on a product certified to the 2014 Edition.

3. Removal of the ONC-Approved Accreditor From the Program

We propose to remove the ONC-Approved Accreditor (ONC–AA) from the Program. The ONC–AA's role is to accredit certification bodies for the Program and to oversee the ONC–ACBs. However, years of experience and changes with the Program have led ONC to conclude that, in many respects, the role of the ONC–AA to oversee ONC–ACBs is now duplicative of ONC's oversight. More specifically, ONC's experience with administering the Principles of Proper Conduct for ONC–ACBs as well as issuing necessary regulatory changes (*e.g.,* ONC–ACB surveillance and reporting requirements in the 2015 Edition final rule) has demonstrated that ONC on its own has the capacity to provide the appropriate oversight of ONC–ACBs. Therefore, we believe removal of the ONC–AA would reduce the Program's administrative complexity and burden.

To implement this proposed deregulatory action, we propose to remove the definition for ''ONC-Approved Accreditor or ONC–AA'' found in § 170.502. We also propose to remove processes related to ONC–AAs found in §§ 170.501(c), 170.503, and 170.504 regarding requests for ONC–AA status, ONC–AA ongoing responsibilities, and reconsideration for requests for ONC–AA status. Regarding correspondence and communication with ONC, we propose to remove specific references to the ''ONC–AA'' and ''accreditation organizations requesting ONC–AA status'' by revising § 170.505. We also propose to remove the final rule titled ''Permanent Certification Program for Health Information Technology; Revisions to ONC-Approved Accreditor Processes'' (76 FR 72636) which established a process for addressing instances where the ONC–AA engages in improper conduct or does not perform its responsibilities under the Program. Because this prior final rule relates solely to the role and removal of the ONC–AA, we propose its removal and § 170.575, which codified the final rule in the CFR.

These proposed deregulatory actions would also provide an additional benefit for ONC–ACBs. ONC–ACBs would be able to obtain and maintain accreditation to ISO/IEC 17065, with an appropriate scope, from any accreditation body that is a signatory to the Multilateral Recognition Arrangement (MLA) with the International Accreditation Forum (IAF). Accordingly, we propose to revise the application process for ONC–ACB status in § 170.520(a)(3) to require documentation that confirms that the applicant has been accredited to ISO/IEC 17065, with an appropriate scope, by any accreditation body that is a signatory to the Multilateral Recognition Arrangement (MLA) with the International Accreditation Forum (IAF), in place of the ONC–AA accreditation documentation requirements. Similarly, instead of requiring the ONC–AA to evaluate the conformance of ONC–ACBs to ISO/IEC 17065, we propose to revise § 170.523(a) to simply require ONC–ACBs to maintain accreditation in good standing to ISO/IEC 17065 for the Program. This means that ONC–ACBs would need to continue to comply with ISO/IEC 17065 and requirements specific to the ONC Health IT Certification Program scheme.

4. Removal of Certain 2015 Edition Certification Criteria and Standards

We have reviewed and analyzed the 2015 Edition to determine whether there are certification criteria we could remove. We have identified both criteria and standards for removal as proposed below. We believe the removal of these criteria and standards will reduce burden and costs for health IT developers and health care providers by eliminating the need to: Design and meet specific certification functionalities; prepare, test, and certify health IT in certain instances; adhere to associated reporting and disclosure requirements; maintain and update certifications for certified functionalities; and participate in surveillance of certified health IT. To these points, if our proposals are finalized in a subsequent final rule, we would expect any already issued 2015 Edition certificates to be updated to reflect the removal of applicable 2015 Edition certification criteria. We welcome comment on the proposed removal of the identified criteria and standards below and any other 2015 Edition criteria and standards we should consider for removal.

a. 2015 Edition Base EHR Definition Criteria

We propose the removal of certain certification criteria from the 2015 Edition that are included in the 2015 Edition Base EHR definition. The removal of these criteria would support burden and cost reductions for health IT developers and health care providers as noted above.

i. Problem List

We propose to remove the 2015 Edition ''problem list'' certification criterion (§ 170.315(a)(6)). The functionality in this criterion was first adopted as a 2011 Edition certification criterion to support the associated meaningful use Stage 1 objective and measure for recording problem list information. In this regard, SNOMED CT® was adopted specifically to support the measure. This 2015 Edition ''problem list'' criterion remains relatively functionally the same as the 2011 Edition and has exactly the same functionally as the 2014 Edition ''problem list'' criterion.

We propose to remove this criterion for multiple reasons. First, this criterion no longer supports the ''recording'' objective and measure of the CMS Promoting Interoperability Programs as such objective and measure no longer exist. Second, the functionality is sufficiently widespread among health care providers since it has been part of certification and the Certified EHR Technology definition since the 2011 Edition and has not substantively changed with the 2015 Edition. Third, we do not believe this functionality would be removed from health IT systems because of our proposal to remove it from the 2015 Edition Base EHR definition. This functionality is essential to clinical care and would be in EHR systems absent certification, particularly considering the limited certification requirements. Fourth, this functionality does not directly support interoperability as the capabilities are focused on internally recording EHI. In this regard, representing problems with SNOMED CT® is part of the USCDI and, thus, better supports interoperability through its availability for access and exchange. Accordingly, we propose to remove the ''problem list'' criterion from the 2015 Edition, including the 2015 Edition Base EHR definition. We note that once removed from the 2015 Edition, the criterion would also no longer be included in the 2015 Edition ''safety-enhanced design'' criterion.

ii. Medication List

We propose to remove the 2015 Edition ''medication list'' certification criterion (§ 170.315(a)(7)). The functionality in this criterion was first adopted as a 2011 Edition certification criterion to support the associated meaningful use Stage 1 objective and measure for recording medication list information. The criterion does not require use of a vocabulary standard to record medications. This 2015 Edition ''medication list'' criterion remains functionally the same as the 2011 Edition and 2014 Edition ''medication list'' criteria.

We propose to remove this criterion for multiple reasons. First, this criterion no longer supports a ''recording'' objective and measure of the CMS Promoting Interoperability Programs as such objective and measure no longer exist. Second, the functionality is sufficiently widespread among health care providers since it has been part of certification and the Certified EHR Technology definition since the 2011 Edition and has not substantively changed with the 2015 Edition. Third, we do not believe this functionality would be removed from EHR systems because of our proposal to remove it from the 2015 Edition Base EHR definition. This functionality is essential to clinical care and would be in EHR systems absent certification, particularly considering the limited certification requirements. Fourth, this functionality does not directly support interoperability as the capabilities are focused on internally recording EHI. In this regard, this criterion does not even require representation of medications in standardized nomenclature. Fifth, medications are included in the USCDI and must be represented in RxNorm as part of the USCDI. This approach better supports interoperability through medication information being availability for access and exchange in a structured format. Accordingly, we propose to remove the ''medications list'' criterion from the 2015 Edition, including the 2015 Edition Base EHR definition. We note that once removed from the 2015 Edition, the criterion would also no longer be included in the 2015 Edition ''safety-enhanced design'' criterion.

iii. Medication Allergy List

We propose to remove the 2015 Edition ''medication allergy list'' certification criterion (§ 170.315(a)(8)). The functionality in this criterion was first adopted as a 2011 Edition certification criterion to support the associated meaningful use Stage 1 objective and measure for recording this information. The criterion does not require use of a vocabulary standard to record medication allergies. This 2015 Edition ''medication allergy list'' criterion remains functionally the same as the 2011 Edition and 2014 Edition ''medication allergy list'' criteria.

We propose to remove this criterion for multiple reasons. First, this criterion no longer supports a ''recording'' objective and measure of the CMS Promoting Interoperability Programs as such objective and measure no longer exist. Second, the functionality is sufficiently widespread among health care providers since it has been part of certification and the Certified EHR Technology definition since the 2011 Edition and has not substantively changed with the 2015 Edition. Third, we do not believe this functionality would be removed from EHR systems because of our proposal to remove it from the 2015 Edition Base EHR definition. This functionality is essential to clinical care and would be in EHR systems absent certification, particularly considering the limited certification requirements. Fourth, this functionality does not directly support interoperability as the capabilities are focused on internally recording EHI. In this regard, this criterion does not even require representation of medication allergies in standardized nomenclature. Fifth, medication allergies are included in the USCDI and must be represented in RxNorm as part of the USCDI. This approach better supports interoperability through medication allergy information being availability for access and exchange in a structured format. Accordingly, we propose to remove the ''medication allergy list'' criterion from the 2015 Edition, including the 2015 Edition Base EHR definition. We note that once removed from the 2015 Edition, the criterion would also no longer be included in the 2015 Edition ''safety- enhanced design'' criterion.

iv. Smoking Status

We propose to remove the 2015 Edition ''smoking status'' criterion (§ 170.315(a)(11)), which would include removing it from the 2015 Edition Base EHR definition. We previously adopted a 2015 Edition ''smoking status'' certification criterion that does not reference a standard. However, the CCDS definition requires smoking status to be coded in accordance with SNOMED CT®. While we continue to believe that the capture of a patient's smoking status has significant value in assisting providers with addressing the number one cause of preventable death

and disease in the United States, we no longer believe that a criterion that simply ensures this functionality exists in health IT presented for certification is the right focus. As with other 2014 Edition functionality, we believe this functionality is fairly ubiquitous now with the widespread adoption of health IT certified to the 2014 Edition. Further, we continue to believe that, for the purposes of certification, having smoking status available for access and exchange via the USCDI is ultimately the key requirement for supporting interoperability.

Removal of Specific USCDI Smoking Status Code Sets

As mentioned above, we believe having smoking status available for USCDI purposes is fundamentally important for supporting interoperability. We propose, however, to remove the requirement to code smoking status according to the adopted eight smoking status SNOMED CT® codes as referenced in the value set in § 170.207(h). These eight codes reflect an attempt to capture smoking status in a consistent manner. Stakeholder feedback has, however, indicated that these eight codes do not appropriately and accurately capture all applicable patients' smoking statuses. Accordingly, we propose to no longer require use of only the specific eight SNOMED CT® codes for representing smoking status (and remove the standard from § 170.207). Rather, to continue to promote interoperability while also granting providers with flexibility to better support clinical care, we propose that health IT would simply be required to be capable of representing smoking status in SNOMED CT® when such information is exchanged as part of the USCDI.

b. Drug-Formulary and Preferred Drug Lists

We propose to remove the 2015 Edition ''drug formulary and preferred drug list checks'' criterion in § 170.315(a)(10). We adopted a 2015 Edition ''drug-formulary and preferred drug list checks'' criterion that separates drug formulary and preferred drug list functionality, but does *not* require any standards or functionality beyond that included in the 2014 Edition ''drug-formulary checks'' criterion. First, we believe this functionality is fairly ubiquitous now with the widespread adoption of health IT certified to the 2014 Edition, which included this general functionality. Second, without standards, this criterion does not support or facilitate the critical goal of health IT interoperability. Therefore, removal of this criterion could reduce health IT developer and health care provider burden.

c. Patient-Specific Education Resources

We propose to remove the 2015 Edition ''patient-specific education resources'' certification criterion (§ 170.315(a)(13)). ONC continues to support patient and provider interaction, and the identification and dissemination of patient-specific educational materials to promote positive health outcomes. However, we no longer believe that certification focused on a health IT's ability to identifying the existence of patient-specific education materials encourages the advancement of this functionality or interoperability. First, this criterion would no longer be associated with an objective or measure under the Promoting Interoperability Programs based on proposals and determinations in recent CMS rulemakings (83 FR 35928; 83 FR 41664). Second, based on the number of health IT products that have been certified for this functionality as part of 2014 Edition certification and already for 2015 Edition certification, we believe that health IT's ability to identify appropriate patient education materials is widespread now among health IT developers and their customers (*e.g.,* health care providers). Third, we have recently seen innovative advancements in this field, including the use of automation and algorithms to provide appropriate educations materials to patients in a timely manner. These advancements help limit clinical workflow interruptions and demonstrate the use and promise of health IT to create efficiencies and improve patient care. As such, removal of this criterion would prevent certification from creating an unnecessary burden for developers and providers and an impediment to innovation.

d. CCDS Summary Record—Create; and CCDS Summary Record—Receive

We assessed the number of products certified to the 2015 Edition ''Common Clinical Data Set summary record—create'' (§ 170.315(b)(4)) and ''Common Clinical Data Set summary record—receive'' (§ 170.315(b)(5)) criteria that have not also been certified to the 2015 Edition ''transitions of care'' criterion (§ 170.315(b)(1)). We did this because the 2015 Edition ''CCDS summary record'' criteria include the same functionality as the 2015 Edition ''transitions of care'' criterion, except for Direct-related transport functionality. Based on our findings of only two unique products certified to these criteria at the time of the drafting of this proposed rule, there appears to be little market demand for certification to them. This outcome is likely attributable to the fact mentioned above regarding their relationship to the 2015 Edition ''transition of care'' criterion, that they are not included in the 2015 Edition Base EHR definition, and that no HHS program specifically requires the use of health IT certified to the criteria. Therefore, we propose to remove these certification criteria from the 2015 Edition.

e. Secure Messaging

We propose to remove the 2015 Edition ''secure messaging'' criterion (§ 170.315(e)(2)). ONC strongly supports patient and provider communication, as well as protecting the privacy and security of patient information. However, we no longer believe that separate certification focused on a health IT's ability to send and receive secure messages between health care providers and patients is necessary. First, this criterion would no longer be associated with an objective or measure under the Promoting Interoperability Programs based on proposals and determinations in recent CMS rulemakings (83 FR 41664; 83 FR 35929). Second, there are multiple other 2015 Edition certification criteria that support patient engagement, such as the 2015 Edition ''view, download, and transmit to 3rd party,'' ''API,'' and ''patient health information capture'' certification criteria. Third, we have seen developers integrate this functionality as part of other patient engagement features, such as patient portals. With these considerations in mind and the lack of a negative impact on health IT interoperability, we believe that the removal of this criterion will help reduce burden and costs, while also spurring further innovations in patient engagement.

5. Removal of Certain ONC Health IT Certification Program Requirements

We propose to remove certain mandatory disclosure requirements and a related attestation requirement under the Program. We believe removal of these requirements will reduce costs and burden for Program stakeholders, particularly health IT developers and ONC–ACBs. We welcome comment on the proposed removal of these requirements and any other certification or Program requirements we should consider for removal.

a. Limitations Disclosures

We propose to remove § 170.523(k)(1)(iii)(B), which requires ONC–ACBs to ensure that certified

health IT includes a detailed description of all known material information concerning limitations that a user may encounter in the course of implementing and using the certified health IT, whether to meet ''meaningful use'' objectives and measures or to achieve any other use within the scope of the health IT's certification. We also propose to remove § 170.523(k)(1)(iv)(B) and (C), which state that the types of information required to be disclosed include, but are not limited to: (B) Limitations, whether by contract or otherwise, on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification; or in connection with any data generated in the course of using any capability to which health IT is certified; (C) Limitations, including but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified.

These disclosure requirements regarding certified health IT limitations are superseded by the Cures Act information blocking provision and Conditions of Certification, which we are implementing with this proposed rule. In particular, section 3001(c)(5)(D)(ii) of the Cures Act requires that a health IT developer, as a Condition of Certification under the Program, provide assurances to the Secretary that, unless for legitimate purposes specified by the Secretary, the developer will not take any action that constitutes information blocking as defined in section 3022(a) of the PHSA, or any other action that may inhibit the appropriate exchange, access, and use of electronic health information. These assurances specifically focus on preventing information blocking and promoting appropriate exchange, access, and use of electronic health information. We further propose adding as a complementary Condition of Certification that developers would be prohibited from taking any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the scope of the technology's certification. Such actions may inhibit the appropriate access, exchange, or use of electronic health information and are therefore contrary to this proposed Condition of Certification and the statutory provision that it implements. Based on these Conditions of Certification, we believe that disclosures of limitations by health IT developers would be unlikely and unnecessary given their prohibition.

b. Transparency and Mandatory Disclosures Requirements

We propose to remove the Principle of Proper Conduct (PoPC) in § 170.523(k)(2), which requires a health IT developer to submit an attestation that it will disclose all of the information in its mandatory disclosures per § 170.523(k)(1) to specified parties (*e.g.,* potential customers or anyone inquiring about a product quote or description of services). We propose that this provision is no longer necessary and that its removal is appropriate to further reduce administrative burden for health IT developers and ONC–ACBs. First, our experience with developer attestations to this requirement is that over 90% of developers with certified health IT have attested that they will provide ''transparency information.'' Second, the information that developers would be asked to attest to, whether our proposal above to remove certain disclosure requirements is finalized or not, is now readily available on health IT developers' websites as the mandatory disclosure requirements were implemented almost three years ago. Therefore, we believe removal of this requirement is appropriate.

6. Recognition of Food and Drug Administration Processes

Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112–144, required that the Food and Drug Administration (FDA), in consultation with ONC and the Federal Communications Commission (FCC) (collectively referred to as ''the Agencies'' [10] for this proposal), develop a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. The FDASIA Health IT Report of April 2014 [11] contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT that promotes innovation, protects patient safety, and avoids regulatory duplication. Public comments, received prior to the report and after,[12] recommended that health IT developers/manufacturers apply a single process that satisfies the requirements of all agencies and that existing safety and quality-related processes, systems, and standards should be leveraged for patient safety in health IT. On July 27, 2017, FDA announced a voluntary Software Precertification (Pre-Cert) Pilot Program as part of a broader Digital Health Innovation Action Plan.[13] It was developed in order to create a tailored approach toward recognizing the unique characteristics of digital technology by looking first at the firm, rather than primarily at each product of the firm, as is currently done for traditional medical products. The FDA plans to explore whether and how pre-certified companies that have demonstrated a culture of quality, patient safety, and organizational excellence could bring certain types of digital health products to market either without FDA premarket review or with a more streamlined FDA premarket review.

a. FDA Software Pre-Certification Pilot Program

ONC believes that health IT developers that hold precertification under the FDA Digital Health Software Precertification Program (FDA Software Precertification Program) when they present health IT for certification under the Program could qualify for, and benefit from, further efficiencies under the Program. Title IV of the Cures Act provides ONC with authority under the Program to oversee health IT developers through Conditions and Maintenance of Certification requirements (*see* section VII Conditions and Maintenance of Certification of this proposed rule). With this new authority and our authority over health IT developers' health IT certified under the Program, we propose to establish processes that would provide health IT developers that can document holding precertification under the FDA Software Precertification Program with exemptions to the ONC Health IT Certification Program's requirements for testing and certification of its health IT to the 2015

[10] ONC is not an agency, but an Office, within the Department of Health and Human Services.

[11] *https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf.*

[12] *https://www.federalregister.gov/documents/2013/05/30/2013-12817/food-and-drug-administration-safety-and-innovation-act-fdasia-request-for-comments-on-the; https://blogs.fda.gov/fdavoice/index.php/2014/04/fda-seeks-comment-on-proposed-health-it-strategy-that-aims-to-promote-innovation/;* and *https://www.regulations.gov/document?D=FDA-2014-N-0339-0001.*

[13] *https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/Default.htm.*

Edition ''quality management systems'' criterion (§ 170.315(g)(4)) and the 2015 Edition ''safety-enhanced design'' criterion (§ 170.315(g)(3)), as these criteria are applicable to the health IT developer's health IT presented for certification. We also believe that such a ''recognition'' could, depending on the final framework of the FDA Software Precertification Program (*e.g.,* the key performance indicators used to demonstrate performance and outcomes of excellence), be applicable to the functionally-based 2015 Edition ''clinical'' certification criteria (§ 170.315(a)). More specifically, this could address the ''computerized provider order entry (CPOE)'' (§ 170.315(a)(1), (2), and (3)), ''drug-drug, drug-allergy interaction checks for CPOE'' (§ 170.315(a)(4)), ''clinical decision support'' (§ 170.315(a)(9)), and ''implantable device list'' (§ 170.315(a)(14)) certification criteria. Such ''recognition'' could also be appropriate to address any or all of the following functionally-based 2015 Edition criteria in the event their proposed removal is not finalized: ''problem list'' (§ 170.315(a)(6)), ''medication list'' (§ 170.315(a)(7)), ''medication allergy list'' (§ 170.315(a)(8)), ''drug-formulary and preferred drug list checks'' (§ 170.315(a)(10)),'' and ''smoking status'' (§ 170.315(a)(11)).

Our proposed ''recognition'' would align with both Executive Orders 13563 and 13771 regarding deregulatory, less burdensome, and more effective initiatives. It would also serve as a regulatory relief for those health IT developers qualifying as small businesses under the Regulatory Flexibility Act (*see* section XIV.C.3 Regulatory Flexibility Act of this proposed rule). Furthermore, it would closely align with FDASIA's instruction to promote innovation, protect patient safety, and avoid regulatory duplication. However, despite these proffered benefits, there may be reasons not to adopt such a ''recognition'' approach. For example, stakeholders may not agree that the FDA Software Precertification Program (and/or subsequent finalized program) sufficiently aligns with our Program. Developers and providers may have varying and divergent views about the benefits and detriments of such an approach. Further, while we believe that we could properly operationalize such an approach by ensuring certifications indicate which criteria have been ''deemed certified'' by ONC (but still subject to ONC–ACB surveillance), stakeholders may have other operational concerns. Accordingly, we welcome comments on these and other aspects of our proposed ''recognition'' approach, including the 2015 Edition certification criteria that should be eligible for ''recognition.''

b. Development of Similar Independent Program Processes—Request for Information

Recognition of the FDA Software Pre-Certification Program for purposes of our Program, as noted above, may eventually be determined to be infeasible or insufficient to meet our goals of reducing burden and promoting innovation. With this in mind, we request comment on whether ONC should establish new regulatory processes tailored towards recognizing the unique characteristics of health IT (*e.g.,* EHR software) by looking first at the health IT developer, rather than primarily at the health IT presented for certification, as is currently done under the Program. For example, ONC could possibly establish Conditions and Maintenance of Certification requirements, through rulemaking, that facilitate the deeming of all of a health IT developer's health IT as ''certified'' under the Program for certification criteria identified by ONC as solely ''functionally-based'' criteria (*i.e.,* not essential to interoperability, such as the ''CPOE'' criteria) or possibly broader in scope. This approach could rely on, but not be limited to, one or a combination of the following: (1) Certain demonstrated health IT developer processes or health IT functionality; (2) prior successful certification of a health IT developer's health IT under the Program; (3) results of real world testing for interoperability as required by the Cures Act and the proposed implementing regulatory Condition of Certification (*see* section VII.B.5 of this proposed rule); and/or (4) the results of the EHR Reporting Program once implemented (*see* section VII.B.7 of this proposed rule). No matter the specifics, we are most interested in whether stakeholders believe this is an approach we should pursue in conjunction with, or in lieu of, the proposed approach of recognizing the FDA Software Pre-Certification Pilot Program. We also welcome more specific comments on the health IT developer criteria for such an approach and what the Conditions and/or Maintenance of Certification requirements should be to support such an approach within the framework of the proposed Conditions and Maintenance of Certification requirements discussed in section VII of this proposed rule.

IV. Updates to the 2015 Edition Certification Criteria

This rule proposes to update the 2015 Edition by revising and adding certification criteria that would establish the capabilities and related standards and implementation specifications for the certification of health IT. The updates to the 2015 Edition would enhance interoperability and improve the accessibility of patient records consistent with section 4006(a) of the Cures Act.

A. Standards and Implementation Specifications

1. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A–119 [14] require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to electing only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. Agencies have the discretion to decline the use of existing voluntary consensus standards if determined that such standards are inconsistent with applicable law or otherwise impractical, and instead use a government-unique standard or other standard. In addition to the consideration of voluntary consensus standards, the OMB Circular A–119 recognizes the contributions of standardization activities that take place outside of the voluntary consensus standards process. Therefore, in instances where use of voluntary consensus standards would be inconsistent with applicable law or otherwise impracticable, other standards should be considered that meet the agency's regulatory, procurement or program needs, deliver favorable technical and economic outcomes, and are widely utilized in the marketplace. In this proposed rule, we use voluntary consensus standards except for:

- The standard we propose to adopt in § 170.213. We propose to remove the Common Clinical Data Set (CCDS) definition and effectively replace it with a government

[14] *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A119/revised_circular_a-119_as_of_1_22.pdf.*

unique standard, the United States Core Data for Interoperability (USCDI), Version 1(v1);

- The standard we propose to adopt in § 170.215(a)(2). We propose the government unique API Resource Collection in Health (ARCH) Version 1 implementation specification;
- The standards we propose to adopt in § 170.215(a)(3) through (5) for application programming interfaces (APIs). These market driven consortia standards have been developed through a streamlined process that does not meet the full definition of voluntary consensus standards development but still includes representation from those interested in the use cases supported by the standards (*e.g.,* health IT developers and health care providers). In the absence of available voluntary consensus standards that would meet our needs, these standards deliver favorable technical and economic outcomes, particularly improved interoperability. Further, some of these standards may eventually proceed through a standards development organization for approval; and
- The standards we propose to adopt in § 170.205(h)(3) and (k)(3). We propose to replace the current HL7 QRDA standards with government unique standards that more effectively support the associated certification criterion's use case, which is reporting eCQM data to CMS.

2. Compliance With Adopted Standards and Implementation Specifications

In accordance with Office of the Federal Register regulations related to ''incorporation by reference,'' 1 CFR part 51, which we follow when we adopt proposed standards and/or implementation specifications in any subsequent final rule, the entire standard or implementation specification document is deemed published in the **Federal Register** when incorporated by reference therein with the approval of the Director of the Federal Register. Once published, compliance with the standard and implementation specification includes the entire document unless we specify otherwise. For example, if we adopted the Argonaut Data Query Implementation Guide (IG) proposed in this proposed rule (*see* section VII.B.4.b), health IT certified to certification criteria referencing this IG would need to demonstrate compliance with all mandatory elements and requirements of the IG. If an element of the IG is optional or permissive in any way, it would remain that way for testing and certification *unless* we specified otherwise in regulation. In such cases, the regulatory text would preempt the permissiveness of the IG.

3. ''Reasonably Available'' to Interested Parties

The Office of the Federal Register has established requirements for materials (*e.g.,* standards and implementation specifications) that agencies propose to incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5(a)). To comply with these requirements, in section XI (''Incorporation by Reference'') of this preamble, we provide summaries of, and uniform resource locators (URLs) to, the standards and implementation specifications we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations. To note, we also provide relevant information about these standards and implementation specifications throughout the relevant sections of the proposed rule.

B. Revised and New 2015 Edition Criteria

In order to capture and share patient data efficiently, health care providers need health IT that store data in structured formats. Structured data allows health care providers to easily retrieve and transfer patient information, and use health IT in ways that can aid patient care. We propose to adopt revised and new 2015 Edition certification criteria, including new standards, to support these objectives. Some of these criteria and standards are included in the Certified EHR Technology (CEHRT) definition used for participation in HHS Programs, such as the Promoting Interoperability Programs (formerly the EHR Incentive Programs), some are required to be met for participation in the ONC Health IT Certification Program, and some, though beneficial, are unassociated with the CEHRT definition and not required for participating in any HHS program, including the ONC Health IT Certification Program.

1. The United States Core Data for Interoperability Standard (USCDI)

The initial focus of the Program was to support the Medicare and Medicaid EHR Incentive Programs (76 FR 1294) now referred to as the Promoting Interoperability Programs (and referenced as such hereafter). As such, the 2014 Edition certification criteria mirrored those functions specified by Promoting Interoperability Programs' objectives and measures. In order to improve efficiency and streamline the common data within our Program's certification criteria, we created a single definition for all the required data which could be referenced for all applicable certification criteria. We created the term ''Common MU Data Set'' to encompass the common set of MU data types/elements (and associated vocabulary standards) for which certification would be required across several certification criteria (77 FR 54170).

The 2015 Edition final rule modified the Program to make it open and accessible to more types of health IT, and health IT that supports various care and practice settings beyond those included in the Promoting Interoperability Programs (80 FR 62604). In comparison to the previous editions, the 2015 Edition focused on identifying health IT components necessary to establish an interoperable nationwide health information infrastructure, fostering innovation and open new market opportunities, and allowing for more health care provider and patient choices in electronic health information access and exchange. In order to align with this approach, we revised the concept of the ''Common MU Data Set'' definition and changed the name to the ''Common Clinical Data Set'' (CCDS) definition. The CCDS definition was further revised in the 2015 Edition rulemaking to account for new and updated vocabulary and content standards in order to improve and advance interoperability and health information exchange (80 FR 62604). It further expanded accessibility and availability of data exchanged by updating the definition of Base Electronic Health Record (EHR) (2015 Edition Base EHR definition) to include enhanced data export, transitions of care, and application programming interface (API) capabilities, all of which required that at a minimum the CCDS be available (80 FR 62602–62604).

The regulatory approach to use and reference a ''definition'' to identify electronic health information, including with associated vocabulary codes, for access, exchange and use has had its drawbacks. While the CCDS definition served its designed purpose, to cut down on repetitive text in each of the certification criteria in which it is referenced, it also began to be colloquially used for many different purposes. As the CCDS definition's relevance grew outside of its regulatory context it became a symbolic and practical limit to the industry's collective interests to go beyond the CCDS data for access, exchange, and use. As we move towards value-based care and the inclusion of data classes that go beyond clinical data, and as part of ONC's continued efforts to evaluate the availability of a minimum baseline of data classes that must be commonly available for interoperable exchange, we acknowledge the need to change and improve our regulatory approach to the CCDS. Therefore, in order to advance interoperability by ensuring compliance with new data and vocabulary codes

sets that support the data, we propose to remove the ''Common Clinical Data Set'' definition and its references from the 2015 Edition and replace it with the ''United States Core Data for Interoperability'' (USCDI) standard. The USCDI standard aims to achieve the goals set forth in the Cures Act by specifying a common set of data classes for interoperable exchange.

We propose to adopt the USCDI as a standard as such term is defined in § 170.102. In § 170.102, a ''standard'' is defined as a ''technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, characteristics, or actions.'' The USCDI standard would comprise data classes, which may be further delineated into groupings of specific data element(s). For example, ''patient demographics'' is a data class and within that data class there is ''patient name,'' which is a data element. As noted in section IV.B.1.b, for the overall structure and organization of the USCDI, please consult *www.healthIT.gov/USCDI.*

ONC intends to establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion. Once the Secretary adopts the first version of the USCDI through rulemaking, which we propose in this rulemaking, health IT developers would be allowed to take advantage of the ''Standards Version Advancement Process'' flexibility. The Standards Version Advancement Process, proposed in Section VII.B.5 (below), would permit health IT developers to voluntarily implement and use a new version of an adopted standard (*e.g.,* the USCDI), subject to certain conditions including a requirement that the new version is approved for use by the National Coordinator.

a. USCDI 2015 Edition Certification Criteria

We propose to adopt the USCDI Version 1 (USCDI v1) in § 170.213. [15] The USCDI is a standardized set of health data classes and constituent data elements that would be required to support nationwide electronic health information exchange. Once adopted in a final rule, health IT developers would be required to update their certified health IT to support the USCDI v1 for all certification criteria affected by this proposed change. We propose to revise the following CCDS dependent 2015 Edition certification criteria to incorporate the USCDI standard:

- ''Transitions of care'' (§ 170.315(b)(1));
- ''view, download, and transmit to 3rd party'' (§ 170.315(e)(1));
- ''consolidated CDA creation performance'' (§ 170.315(g)(6));
- ''transmission to public health agencies—electronic case reporting'' (§ 170.315(f)(5)); and
- ''application access—all data request'' (§ 170.315(g)(9)).

We note that we did not include the ''data export'' criterion (§ 170.315(b)(6)) as we are proposing to remove it and adopt instead the ''EHI export'' criterion (§ 170.315(b)(10)). For similar reasons, we did not include the ''application access—data category request'' criterion (§ 170.315(g)(8)) because we are proposing to replace it with the API certification criterion (§ 170.315(g)(10)), which derives its data requirements from the USCDI.

We propose, as a Maintenance of Certification requirement for the real world testing Condition of Certification, that health IT developers with health IT certified to the five above-identified certification criteria prior to the effective date of a subsequent final rule would have to update such certified health IT to the proposed revisions. We further propose, as a Maintenance of Certification requirement for the real world testing Condition of Certification, that health IT developers must provide the updated certified health IT to all their customers with health IT previously certified to the identified criteria no later than 24 months after the effective date of a final rule for this proposed rule. For the purposes of meeting this compliance timeline, we expect health IT developers to update their certified health IT without new mandatory testing and notify their ONC–ACB on the date at which they have reached compliance. Developers would also need to factor these updates into their next real world testing plan as discussed in section VII.B.5 of this proposed rule. Further, we refer health IT developer to the next section, which describes how the USCDI differs from the current CCDS.

b. USCDI Standard—Data Classes Included

The USCDI Version 1 (USCDI v1) and its constituent data elements account for the public comments we received on the Draft USCDI and Proposed Expansion Process[16] published in January 2018 as well as initial feedback from the Health IT Advisory Committee. The standard as we propose to adopt it in § 170.213 also reflects and acknowledges the burden that rapidly expanding the USCDI v1 beyond the CCDS could cause. As a result, the USCDI v1 is a modest expansion of the CCDS, which we believe most health IT developers already support, were already working toward, or should be capable of updating their health IT to support in a timely manner. The following describes only the delta between the CCDS and the USCDI v1. For the overall structure and organization of the USCDI standard, please consult *www.healthIT.gov/USCDI.*

i. Updated Versions of Vocabulary Standard Code Sets

We propose that the USCDI Version 1 (USCDI v1) include the newest versions of the ''minimum standard'' code sets included in the CCDS available at publication of a subsequent final rule. We request comment on this proposal and on whether this could result in any interoperability concerns. To note, criteria such as the 2015 Edition ''family health history'' criterion (§ 170.315(a)(12)), the 2015 Edition ''transmission to immunization registries'' criterion (§ 170.315(f)(1)), and the 2015 Edition ''transmission to public health agencies—syndromic surveillance'' criterion (§ 170.315(f)(2)) reference ''minimum standard'' code sets; however, we are considering changing the certification baseline versions of the code set for these criteria from the versions adopted in the 2015 Edition final rule to ensure complete interoperability alignment. We welcome comment on whether we should adopt such an approach.

We also note, for purposes of clarity, that consistent with § 170.555, unless the Secretary prohibits the use of a newer version of an identified minimum standard code set for certification, health IT could continue to be certified or upgraded to a newer version of an identified minimum standard code set than that included in USCDI v1 or the most recent USCDI version that the National Coordinator has approved for use in the Program via the Standards Version Advancement Process.

ii. Address and Phone Number

The USCDI v1 includes new data elements for ''address'' and ''phone number.'' The inclusion of ''address'' (to represent the postal location for the

[15] We note that USCDI v1is an updated version and distinguished from the *Draft United States Core Data for Interoperability (USCDI)* previously made available for public review and comment in the course of its development as a prospective standard.

[16] *https://www.healthit.gov/sites/default/files/draft-uscdi.pdf.*

patient) and ''phone number'' (to represent the patient's telephone number) would improve the comprehensiveness of health information for patient care. The inclusion of these data elements is also consistent with the list of patient matching data elements already specified in the 2015 Edition ''transitions of care'' certification criterion (§ 170.315(b)(1)(iii)(G)), which supports the exchange of patient health information between providers of patient care.

iii. Pediatric Vital Signs

The USCDI v1 includes the pediatric vital sign data elements, which are specified as optional health information in the 2015 Edition CCDS definition. Pediatric vital signs include: Head occipital-frontal circumference for children less than 3 years of age, BMI percentile per age and sex for youth 2–20 years of age, weight for age per length and sex for children less than 3 years of age, and the reference range/scale or growth curve, as appropriate. As explained in section VI.A.2 of this proposed rule, the inclusion of pediatric vital sign data elements in the draft USCDI v1 would align with the provisions of the Cures Act related to health IT to support the health care of children. Stakeholders emphasized the value of pediatric vital sign data elements to better support the safety and quality of care delivered to children. We also note that, as discussed in the 2015 Edition proposed rule, the Centers for Disease Control and Prevention (CDC) recommends the use of these pediatric vital signs for settings of care in which pediatric and adolescent patients are seen (80 FR 16818–16819) as part of best practices. The availability of a reference range/scale or growth curve would help with proper interpretation of the measurements for the BMI percentile per age and sex and weight for age per length and sex. Further, the inclusion of this health information in the USCDI v1 is the appropriate next step after first specifying them as optional in the CCDS definition as part of the 2015 Edition rulemaking and as a means of supporting patient access to their EHI in a longitudinal format through certified health IT (*see* section 3009(e)(2)(A)(i) of the PHSA as amended by the Cures Act). We recognize, however, that certain health IT developers and their customers may not find these capabilities and information useful. Therefore, we request comment on the inclusion of pediatric vital signs in the USCDI v1, including the potential benefits and costs for all stakeholders stemming from its inclusion in the USCDI v1.

iv. Clinical Notes

The USCDI v1 includes a new data class, titled ''clinical notes.'' ''Clinical notes'' is included in the USCDI v1 based on significant feedback from the industry since the 2015 Edition final rule. We also received feedback during the Trusted Exchange Framework and Common Agreement (TEFCA) stakeholder sessions and public comment period. It has been identified by stakeholders as highly desirable data for interoperable exchange. The free text portion of the clinical notes was most often relayed by clinicians as the data they sought, but were often missing during electronic health information exchange. Clinical notes can be composed of text generated from structured (pick-list and/or check the box) fields as well as unstructured (free text) data. A clinical note may include the assessment, diagnosis, plan of care and evaluation of plan, patient teaching, and other relevant data points.

We recognize that a number of different clinical notes could be useful for stakeholders. It is our understanding that work is being done in the community to focus on a subset of clinical notes. We considered three options for identifying the different ''note types'' to adopt in USCDI v1. The first option we considered would allow for the community to offer any and all recommended notes. The second option we considered would set a minimum standard of eight note types. This option was derived from the eight note types identified by the Argonaut Project participants.[17] The third option we identified would look to the eleven HL7 Consolidated Clinical Data Architecture (C–CDA) document types identified in the C–CDA Release 2.1, which also included the note types being identified by the Argonaut Project participants. We ultimately decided to move forward with the second option because it unites public and private interests toward the same goal. The eight selected note types are a minimum bar and, in the future, the USCDI may be updated to include other clinical notes. Specifically, we propose to include the following clinical note types for both inpatient and outpatient (primary care, emergency department, etc.) settings in USCDI v1 as a minimum standard: (1) Discharge Summary note; (2) History & Physical; (3) Progress Note; (4) Consultation Note; (5) Imaging Narrative; (6) Laboratory Report Narrative; (7) Pathology Report Narrative; and (8) Procedures Note. We seek comment on whether to include additional note types as part of the USCDI v1.

v. Provenance

The USCDI v1 also includes a new data class, titled ''provenance.'' ''Provenance'' has been identified by stakeholders [18] as valuable for interoperable exchange. The provenance of data was also referenced by stakeholders as a fundamental need to improve the trustworthiness and reliability of the data being exchanged. Provenance describes the metadata, or extra information about data, that can help answer questions such as when and who created the data.

The inclusion of ''provenance'' as a data class in the USCDI v1 would also complement the Cures Act requirement to support the exchange of data through the use of APIs. This approach differs from the exchange of data via the C–CDA. While C–CDAs are often critiqued due to their relative ''length,'' the C–CDA represents the output of a clinical encounter and includes relevant context. The same will not always be true in an API context. APIs facilitate the granular exchange of data and, as noted in the 2015 Edition final rule, offer the potential to aggregate data from multiple sources in a web or mobile application (80 FR 62675). The inclusion of provenance would help retain the relevant context so the recipient can better understand the origin of the data. As noted in section VII.B.4, we are also proposing to include provenance in our proposed ''API Resource Collection in Health'' (ARCH) Version 1 implementation specification in § 170.215(a)(2), which would list a set of base Fast Healthcare Interoperability Resources (FHIR®) resources that Health IT Modules certified to the proposed API criterion (§ 170.315(g)(10)) would need to support.

We propose to further delineate the provenance data class into three data elements: ''the author,'' which represents the person(s) who is responsible for the information; ''the author's time stamp,'' which indicates the time the information was recorded; and ''the author's organization,'' which would be the organization the author is associated with at the time they interacted with the data. We have identified these three data elements as fundamental for data recipients to have

[17] Link to the Clinical Notes Argonaut Project identified (to clarify: Seven bullets are listed, however, we split laboratory and pathology note types into their own note) *http://wiki.hl7.org/index.php?title=201805_Clinical_Notes_Track.*

[18] *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

available and both are commonly captured and currently available through standards. We request comment on the inclusion of these three data elements and whether any other provenance data elements, such as the identity of the individual or entity the data was obtained from or sent by (sometimes discussed in standards working groups as the provenance of the data's ''last hop''), would be essential to include as part of the USCDI v1 standard. We acknowledge that there is currently work to help define provenance in a standard robust manner, and we anticipate adopting the industry consensus once it becomes available.

vi. Unique Device Identifier(s) for a Patient's Implantable Device(s)

We are aware of a recently published implementation guide (IG) within HL7 that provides further guidance on the unique device identifier (UDI) requirements. The IG, Health Level 7 (HL7®) CDA R2 Implementation Guide: C–CDA Supplemental Templates for Unique Device Identification (UDI) for Implantable Medical Devices, Release 1–US Realm,[19] identifies changes needed to the C–CDA to better facilitate the exchange of the individual UDI components in the health care system when devices are implanted in a patient. The UDI components include the Device Identifier (DI) and the following individual production identifiers: The lot or batch number, serial number, manufacturing date, expiration date, and distinct identification code. However, as this new IG has been recently published, we request comment on whether we should add this UDI IG as a requirement for health IT to adopt in order to meet the requirements for UDI USCDI Data Class. In addition, we do not have a reliable basis on which to estimate how much it would cost to meet the requirements outlined in the UDI IG; and, therefore, we request comment on the cost and burden of complying with this proposed requirement.

vii. Medication Data Request for Comment

The USCDI v1 ''Medication'' data class includes two constituent data elements within it: Medications and Medication Allergies. With respect to the latter, Medication Allergies, we request comment on an alternative approach. This alternative would result in removing the Medication Allergies data element from the Medication data class and creating a new data class titled, ''Substance Reactions,'' which would be meant to be inclusive of ''Medication Allergies.'' The new ''Substance Reactions'' data class would include the following data elements: ''Substance'' and ''Reaction,'' and include SNOMED CT as an additional applicable standard for non-medication substances.

c. USCDI Standard—Relationship to Content Exchange Standards and Implementation Specifications

In order to align with our approach to be responsive to the evolution of standards and to facilitate updates to newer versions of standards, the USCDI v1 (§ 170.213) is ''content exchange'' standard agnostic. It establishes ''data policy'' and does not directly associate with the content exchange standards and implementation specifications which, given a particular context, may be necessary to exchange the entire USCDI, a USCDI class, or elements within it. To our knowledge, all data classes in the USCDI v1 can be supported by commonly used ''content exchange'' standards, including HL7 C–CDA Release 2.1 and FHIR®.

d. Clinical Notes C–CDA Implementation Specification

In conjunction with our proposal to adopt the USCDI v1, we propose to adopt the HL7 CDA® R2 IG: C–CDA Templates for Clinical Notes R1 Companion Guide, Release 1 in § 170.205(a)(4)(i) (''C–CDA Companion Guide''). The C–CDA Companion Guide provides supplemental guidance and additional technical clarification for specifying data in the C–CDA Release 2.1.[20] As noted above, the proposed USCDI v1 includes new data classes, such as ''clinical notes,'' which are further supported through the C–CDA Companion Guide. For example, the C–CDA Companion Guide provides specifications for clinical notes by indicating that clinical notes should be recorded in ''note activity'' and requires references to other discrete data, such as ''encounters.'' The C–CDA Companion Guide also enhances implementation of the 2015 Edition certification criteria that reference the C–CDA Release 2.1 (§ 170.205(a)(4)). As noted by stakeholders, the C–CDA Release 2.1 includes some optionality and ambiguity with respect to data element components, such as the locations and value sets. We attempted to address some of this optionality by clarifying requirements using Certification Companion Guides (CCGs)[21] and by specifying in the CCDS definition where certain data should be placed in the C–CDA Release 2.1 templates (*e.g.,* ''goals'' in the goals section).[22] The C–CDA Companion Guide, which was released after the 2015 Edition final rule, provides similar, but additional C–CDA implementation structure. For example, race and ethnicity are required data elements in the USCDI (formerly the CCDS) and must be included in C–CDA exchanges if known, or they may be marked with a nullFlavor of UNK (unknown) if not known. The C–CDA Release 2.1 is unclear on the location and value set, but the C–CDA Companion Guide clarifies the location and value set. The adoption of the C–CDA Companion Guide would align with our goal to increase the consistent implementation of standards among health IT developers and improve interoperability. We propose to adopt this C–CDA Companion Guide to support best practice implementation of USCDI v1 data classes and 2015 Edition certification criteria that reference C–CDA Release 2.1 (§ 170.205(a)(4)). The criteria include:

- ''Transitions of care'' (§ 170.315(b)(1));
- ''clinical information reconciliation and incorporation'' (§ 170.315(b)(2));
- ''care plan'' (§ 170.315(b)(9));
- ''view, download, and transmit to 3rd party'' (§ 170.315(e)(1));
- ''consolidated CDA creation performance'' (§ 170.315(g)(6)); and
- ''application access—all data request'' (§ 170.315(g)(9)).

We propose, as a Maintenance of Certification requirement for the real world testing Condition of Certification, that health IT developers with health IT certified to the six above-identified certification criteria prior to the effective date of a subsequent final rule would have to update such certified health IT to the proposed revisions. We further propose, as a Maintenance of Certification requirement for the real world testing Condition of Certification, that health IT developers must provide the updated certified health IT to all their customers with health IT previously certified to the identified criteria no later than 24 months after the effective date of a final rule for this proposed rule. For the purposes of meeting this compliance timeline, we expect health IT developers to update their certified health IT without new mandatory testing and notify their

[19] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=486.*

[20] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=447.*

[21] *https://www.healthit.gov/topic/certification-ehrs/2015-edition-test-method.*

[22] *https://www.healthit.gov/sites/default/files/topiclanding/2018-04/2015Ed_CCG_CCDS.pdf.*

ONC–ACB on the date at which they have reached compliance. Developers would also need to factor these updates into their next real world testing plan as discussed in section VII.B.5 of this proposed rule.

2. Electronic Prescribing Standard and Certification Criterion

We propose to update the electronic prescribing (e-Rx) SCRIPT standard used for ''electronic prescribing'' in the 2015 Edition to NCPDP SCRIPT 2017071, which would result in a new e-Rx standard becoming the baseline for certification. We propose to adopt this standard in § 170.205(b)(1). ONC and CMS have historically maintained complementary policies of aligning health IT certification criteria and associated standard for e-prescribing with the CMS Medicare Part D e-Rx and MH standards (75 FR 44589; 77 FR 54198). To this end, CMS has retired the current standard (NCPDP SCRIPT version 10.6) for e-RX and MH and adopted NCPDP SCRIPT 2017071 as the standard for Part D e-Rx and MH effective January 1, 2020, conditional on ONC updating the Program to the NCPDP SCRIPT 2017071 standard for its e-Rx certification criterion (*see also* 42 CFR 423.160(b)(1)(v) and (2)(iv)). In addition, CMS recently sought comment regarding whether the NCPDP SCRIPT 2017071 standard could facilitate future reporting of the proposed Query of Prescription Drug Monitoring Program (PDMP) measure in both the 2019 Physician Fee Schedule proposed rule (83 FR 35923) and Hospital Inpatient Prospective Payment Systems (IPPS) Fiscal Year 2019 proposed rule (83 FR 20528).

As summarized in the IPPS Fiscal Year 2019 final rule (83 FR 41144), CMS received comments supportive of using the NCPDP SCRIPT 2017071 medication history transactions for PDMP queries and responses, as well as comments asking CMS to seek harmonizing of the 2015 Edition e-prescribing certification criterion to the NCPDP SCRIPT 2017071 standard specified in the part D program portions of the recent ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' final rule (83 FR 16440).

In addition to proposing to adopt the NCPDP SCRIPT 2017071 standard for the transactions that are listed in the current ''electronic prescribing'' criterion (§ 170.315(b)(3)), we propose to adopt and require conformance to all of the NCPDP SCRIPT 2017071 standard transactions CMS adopted at 42 CFR 423.160(b)(2)(iv) for NCPDP SCRIPT 2017071. Therefore, we propose to adopt a new 2015 Edition ''electronic prescribing'' criterion (§ 170.315(b)(11)) that includes the following transactions:

- Create new prescriptions (NewRx, NewRxRequest, NewRxResponseDenied)

A NewRx transaction is a new prescription from a prescriber to a pharmacy so that it can be dispensed to a patient. A NewRxRequest is a request from a pharmacy to a prescriber for a new prescription for a patient. A NewRxResponseDenied is a denied response to a previously sent NewRxRequest (if approved, a NewRx would be sent). A NewRxResponseDenied response may occur when the NewRxRequest cannot be processed or if information is unavailable.

- Change prescriptions (RxChangeRequest, RxChangeResponse)

An RxChangeRequest transaction originates from a pharmacy to request: A change in the original prescription (new or fillable), validation of prescriber credentials, a prescriber to review the drug requested, or a prior authorization from the payer for the prescription. An RxChangeResponse transaction originates from a prescriber to respond: To a prescription change request from a pharmacy, to a request for a prior authorization from a pharmacy, or to a prescriber credential validation request from a pharmacy.

- Cancel prescriptions (CancelRx, CancelRxResponse)

A CancelRx transaction is a request from a prescriber to a pharmacy to not fill a previously sent prescription. A CancelRx must contain pertinent information for the pharmacy to be able to find the prescription in their system (patient, medication (name, strength, dosage, form), prescriber, prescription number if available). A CancelRxResponse is a response from a pharmacy to a prescriber to acknowledge a CancelRx, and is used to denote if the cancellation is Approved or Denied.

- Renew prescriptions (RxRenewalRequest, RxRenewalResponse)

An RxRenewalRequest transaction originates from a pharmacy to request additional refills beyond those originally prescribed. RxRenewalResponse originates from a prescriber to respond to the request.

- Receive fill status notifications (RxFill, RxFillIndicatorChange)

An RxFill transaction is sent from a pharmacy to a prescriber or a long term or post-acute care (LTPAC) facility indicating the FillStatus (dispensed, partially dispensed, not dispensed or returned to stock, transferred to another pharmacy) of the new, refill, or resupply prescriptions for a patient. RxFillIndicator informs the pharmacy of the prescriber's intent for fill status notifications for a specific patient/medication. An RxFillIndicatorChange is sent by a prescriber to a pharmacy to indicate that the prescriber is changing the types of RxFill transactions that were previously requested, where the prescriber may modify the fill status of transactions previously selected or cancel future RxFill transactions.

- Request and receive medication history (RxHistoryRequest, RxHistoryResponse)

An RxHistoryRequest transaction is a request from a prescriber for a list of medications that have been prescribed, dispensed, claimed, or indicated by a patient. This request could be sent to a state Prescription Drug Monitoring Program (PDMP). An RxHistoryResponse is a response to an RxHistoryRequest containing a patient's medication history. It includes the medications that were dispensed or obtained within a certain timeframe, and optionally includes the prescriber that prescribed it. RxHistoryRequest and RxHistoryResponse transactions may be sent directly or through an intermediary.

- Ask the Mailbox if there are any transactions (GetMessage)

This transaction is used by the prescriber or pharmacy asking the mailbox if there are any transactions. It is at the heart of the mechanism used by a pharmacy or prescriber system to receive transactions from each other or from a payer or the REMS Administrator via a Switch, acting as a Mailbox.

- Relay acceptance of a transaction back to the sender (Status)

This transaction is used to relay acceptance of a transaction back to the sender. A Status in response to any applicable transaction other than GetMessage indicates acceptance and responsibility for a request. A Status in response to GetMessage indicates that no mail is waiting for pickup. A Status cannot be mailboxed and may not contain an error.

- Respond that there was a problem with the transaction (Error)

This transaction indicates an error has occurred, indicating the request was

terminated. An Error can be generated when there is a communication problem or when the transaction actually had an error. An error can be mailboxed, as it may be signifying to the originator that a transaction was unable to be delivered or encountered problems in the acceptance. The Error must be a different response than a Status, since the communication between the system and the Mailbox must clearly denote the actions taking place. An Error is a response being delivered on behalf of a previous transaction, and the Status signifies no more mail.

- Respond that a transaction requesting a return receipt has been received (Verify)

This transaction is a response to a pharmacy or prescriber indicating that a transaction requesting a return receipt has been received. Verifications results when a ''return receipt requested'' flag is set in the original request. Upon receiving a transaction with ReturnReceipt set, it is the responsibility of the receiver to either generate a Verify in response to the request (recommended) or generate a Status in response to this request, followed subsequently by a free standing Verify. This transaction notifies the originator that the transaction was received at the software system. It is not a notification of action taking place, since time may elapse before the ultimate answer to the transaction may take place.

- Request to send an additional supply of medication (Resupply)

This transaction is a request from a Long Term or Post-Acute Care (LTPAC) organization to a pharmacy to send an additional supply of medication for an existing order. An example use case is when a medication supply for a resident is running low (2–3 doses) and a new supply is needed from the pharmacy, the LTPAC organization need a way to notify the pharmacy that an additional supply for the medication is needed.

- Communicate drug administration events (DrugAdministration)

This transaction communicates drug administration events from a prescriber/care facility to the pharmacy or other entity. It is a notification from a prescriber/care facility to a pharmacy or other entity that a drug administration event has occurred—for example, a medication was suspended or administration was resumed.

- Transfer one or more prescriptions (RxTransferRequest, RxTransferResponse, RxTransferConfirm)

The RxTransferRequest transaction is used when the pharmacy is asking for a transfer of one or more prescriptions for a specific patient to the requesting pharmacy. The RxTransferResponse transaction is the response to the RxTransferRequest which includes the prescription(s) being transferred or a rejection of the transfer request. It is sent from the transferring pharmacy to the requesting pharmacy. The RxTransferConfirm transaction is used by the pharmacy receiving (originally requesting) the transfer to confirm that the transfer prescription has been received and the transfer is complete.

- Recertify the continued administration of a medication order (Recertification)

This transaction is a notification from a facility, on behalf of a prescriber, to a pharmacy recertifying the continued administration of a medication order. An example use is when an existing medication order has been recertified by the prescriber for continued use. Long term or post-acute care use only.

- Complete Risk Evaluation and Mitigation Strategy (REMS) Transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse)

With CMS' recent adoption of these transactions in their recently issued final rule associated with e-prescribing for Medicare Part D (42 CFR 423.160(b)(2)(iv)(W)–(Z)), we believe that it would be equally beneficial to include these four REMS transactions as part of this proposed certification criterion: REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse.

The Food and Drug Administration Amendments Act (FDAAA) of 2007 (Pub. L. 110–85) enables the Food and Drug Administration (FDA) to require a REMS from a pharmaceutical manufacturer if the FDA determines that a REMS is necessary to ensure the benefits of a drug outweigh the risks associated with the drug. The currently approved REMS programs vary in levels of complexity. Typically a Med Guide and Communication Plan is required, but some also require Elements to Assure Safe Use (ETASU). The large majority of existing REMS programs are for drugs dispensed through specialty pharmacies, clinics, and hospitals, but as REMS become more common they may ultimately have a greater impact on retail-based products.

The impact of REMS is twofold. First, REMS with ETASU may require the pharmacist to verify prescriber, patient, and/or pharmacy enrollment in a registry and, in some cases, verify or check certain information, such as lab results. Second, all REMS, including those without ETASU, must fulfill FDA-approved reporting requirements. Each REMS program must also include a program assessment schedule that examines the program's effectiveness on intervals approved by the FDA as part of the overall REMS program. The results of these assessments are submitted to the FDA as part of the ongoing evaluation of REMS program effectiveness. Accordingly, we propose to include the REMS transactions as part of this proposed certification criterion. We would also note for commenters' benefit that the SCRIPT 2017071 testing tool under development is being designed to support testing these REMS transactions.

We believe that removing the 2015 Edition certification criterion (codified in § 170.315(b)(3)) that references NCPDP SCRIPT version 10.6 and replacing it with an updated e-prescribing criterion (proposed to be codified in § 170.315(b)(11)) would harmonize with relevant CMS program timelines, including Part D e-prescribing requirements and the option for eligible clinicians, hospitals, and CAHs to report on the Query of Prescription Drug Monitoring Program (PDMP) quality measure for Promoting Interoperability Programs. However, should our proposal to adopt the new e-prescribing criterion (§ 170.315(b)(11)) be finalized prior to January 1, 2020, we also propose to permit continued certification to the current 2015 Edition ''electronic prescribing'' criterion (§ 170.315(b)(3)) for the period of time in which it would continue to be used as a program standard in the CMS Medicare Part D Program or the CMS Promoting Interoperability Programs. Once it is no longer used in those Programs, we would no longer permit certification to that criterion and would remove it from the Code of Federal Regulations. We will consider setting an effective date for such actions in a subsequent final rule based on stakeholder feedback and CMS policies at the time. To this point, we note that the continued acceptability of a Health IT Module certified to the criterion codified in § 170.315(b)(3) for purposes of meeting the CEHRT definition and participating in the CMS Promoting Interoperability Programs would be a matter of CMS policy.

3. Clinical Quality Measures—Report Criterion

In the 2015 Edition final rule, ONC adopted four clinical quality measure (CQM) certification criteria, § 170.315(c)(1) CQMs—record and

export, § 170.315(c)(2) CQMs—import and calculate, § 170.315(c)(3) CQMs—report, and § 170.315(c)(4) CQMs—filter (80 FR 62649–62655). These four criteria were adopted with the intent to support providers' quality improvement activities and in electronically generating CQM reports for reporting with certified health IT to programs such as the EHR Incentive Programs, Quality Payment Program, and Comprehensive Primary Care plus initiative. All four CQM criteria require certified health IT to be capable of generating CQM reports using the HL7 Quality Reporting Document Architecture (QRDA) Category I standard, which provides CQM reports for individual patients. Specifically, we adopted HL7 CDA® Release 2 Implementation Guide for: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, Draft Standard for Trial Use (DSTU) Release 3 (US Realm)), Volume 1 (§ 170.205(h)(2)). Two of the CQM criteria, CQMs—report (§ 170.315(c)(3)) and CQMs—filter (§ 170.315(c)(4)), also require certified health IT to be capable of generating CQM reports using the QRDA Category III standard, which provides aggregate CQM reports for a set of patients. More specifically, we adopted QRDA Category III, Implementation Guide for CDA Release 2 (§ 170.205(k)(1)) and the Errata to the HL7 Implementation Guide for CDA® Release 2: QRDA Category III, DSTU Release 1 (US Realm), September 2014 (§ 170.205(k)(2)).

The ''CQMs—report'' certification criterion (§ 170.315(c)(3)) includes an optional certification provision for demonstrating that the health IT can create QRDA reports in the form and manner required for submission to CMS programs, which is in accordance with CMS' QRDA Implementation Guide (IGs).[23] The CMS QRDA IGs include specific requirements to support providers participating in CMS programs in addition to the HL7 IGs. At the time of the finalization of the 2015 Edition final rule and in response to public comment, we noted that there was mixed feedback on whether this criterion should require adherence to the HL7 QRDA Category I and Category III standards or solely to the CMS QRDA IGs. As such, we adopted an approach that allowed for flexibility and only required that certified health IT support the HL7 QRDA standards, which are program-agnostic and can support a number of use cases for exchanging CQM data. Because the criterion has the optional provision for CMS program-specific certification, developers can also support their end-users who intend to use their certified health IT to report eCQMs to CMS in the ''form and manner'' CMS requires (*i.e.,* using the format specified in the CMS QRDA IGs) (80 FR 62652).

Since the 2015 Edition final rule was published (October 16, 2015), we have gained additional certification experience and received feedback from the industry that health IT certified to the ''CQMs-report'' criterion (§ 170.315(c)(3)) are only/primarily being used to submit eCQMs to CMS for participation in CMS programs. Therefore, as a means of reducing burden, we propose to remove the HL7 QRDA standard requirements from the 2015 Edition CQMs—report criterion in § 170.315(c)(3), but *require* that health IT certified to the criterion support the CMS QRDA IGs. This would directly reduce burden on health IT developers and indirectly providers as they would no longer have to, in practice, develop (health IT developers) and support (both developers and providers) two forms of the QRDA standard (*i.e.,* the HL7 and CMS forms). We note that the Fast Health Interoperability Resources (FHIR) standard offers the potential for supporting quality improvement and reporting needs and promises to be a more efficient, modular, and interoperable standard to develop, implement, and utilize through APIs. However, until the potential benefits of FHIR APIs can be realized for quality improvement and reporting, we believe that solely requiring the CMS QRDA IGs for the ''CQMs—report'' criterion balances the burden to developers and providers, while still meeting the goal of facilitating quality improvement and reporting to CMS.

To support the proposal, we propose to incorporate by reference the latest annual CMS QRDA IGs, specifically the 2019 CMS QRDA I Implementation Guide for Hospital Quality Reporting[24] and the 2019 CMS QRDA III Implementation Guide for Eligible Professionals (EPs) and Eligible Clinicians.[25] A Health IT Module would need to be certified to both standards to provide flexibility to providers. However, we solicit comment on whether we should consider an approach that permits certification to only one of the standards depending on the care setting for which the product is designed and implemented. We also solicit comment on the future possibility of FHIR-enabled APIs replacing or complementing QRDA reports for quality reporting and improvement.

If we finalize this proposal in a subsequent final rule, we propose to adopt the latest CMS QRDA IGs at the time of final rule publication, as CMS updates their QRDA IGs annually to support the latest eCQM specifications and only accepts eCQM reporting to the latest version.

We note that this approach would also facilitate a means for ONC to permit developers to update its certified health IT to newer versions of the CMS QRDA IGs through the real world testing Maintenance of Certification provision for standards and implementation specification updates in support of ongoing interoperability (*see* section VII.B.5 of this proposed rule).

4. Electronic Health Information Export

We propose to adopt a new 2015 Edition certification criterion for EHI export in § 170.315(b)(10). This criterion is intended to provide patients and health IT users with a means to efficiently export the entire electronic health record for a single patient or all patients in a computable, electronic format, and facilitate the receiving health IT system's interpretation and use of the EHI, to the extent reasonably practicable using the developer's existing technology.

This outcome would promote access, exchange, and use of EHI and facilitate health care providers' ability to switch health IT systems or to migrate EHI for use in other technologies. Additionally, as discussed in section VII.B.2 of this preamble, certification to this criterion would provide some degree of assurance that a health IT developer supports, and does not inhibit, the access, exchange, and use of EHI for the specific use cases that the criterion addresses.

This proposed criterion supports two specific use cases for which we believe that all EHI produced and electronically managed in a developer's technology should be made readily available for export as a standard capability of certified health IT.

First, we propose that health IT certified to this criterion would have to enable the export of EHI for a single patient upon a valid request from that patient or a user on the patient's behalf. This patient-focused export capability, which is discussed in more detail below, complements other provisions of this proposed rule that support patients' access to their EHI including information that may eventually be

[23] *https://ecqi.healthit.gov/qrda-quality-reporting-document-architecture.*

[24] *https://ecqi.healthit.gov/system/files/QRDA_HQR_2019_CMS_IG_final_508.pdf.*

[25] *https://ecqi.healthit.gov/system/files/2019_CMS_QRDA_III_Eligible_Clinicians_and_EP_IG-508.pdf.*

accessible via the APIs described in section VII.B.4 of this preamble. Ultimately, we expect all data to be transferred through APIs or other advanced technologies. EHI export also supports longitudinal data record development, and aligns with section 4006(a) of the Cures Act, which requires [t]he Secretary, in consultation with the National Coordinator, [to] promote policies that ensure that a patient's EHI is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent.

Second, this criterion would support the export of EHI when a health care provider chooses to transition or migrate information to another health IT system. As discussed in section VIII.C.5.c.iii of this preamble, health IT developers are in a unique position to block the export and portability of data for use in competing systems or applications, or to charge rents for access to the basic technical information needed to facilitate the conversion or migration of data for these purposes. By providing at least a baseline capability for exporting EHI in a commercially reasonable format, we believe that this criterion would help to address some of these business practices and enable smoother transitions between health IT systems.

This criterion is intended to further the two use cases outlined above while providing an incremental approach given the known and anticipated health IT landscape when ONC expects certified health IT with this functionality will be widely available in the ecosystem. At the time of this rulemaking, we believe a focused certification criterion that is standards-agnostic will provide a useful first step to enabling patients to request and receive their EHI and for providers to more readily switch or migrate information between health IT systems. Understanding that open, standards-based APIs are an emerging technology and that some health IT developers today have implemented proprietary APIs, this proposed criterion for EHI export provides an initial method for exporting patient health information in these circumstances. Over time, ONC may consider expanding the proposed criterion or replacing it to achieve the goals in § 170.402. It is also possible that in the future, this criterion will no longer be needed once standards-based APIs are widely available in the health IT ecosystem with the ability to facilitate exchange of a wider set of standardized data elements per the predictable, transparent, and collaborative process to expand the USCDI (*see* the discussion of the API Condition of Certification and the proposed API criterion in § 170.315(g)(10) in VII.B.4 for additional information).

a. Patient Access

As noted above, the export functionality required by this certification criterion would support both a patient's access to their EHI and a provider's ability to switch to another health IT system. In the patient access context, we propose that a user must be able to timely execute the single patient EHI export at any time the user chooses and without subsequent developer assistance to operate. The health IT developer should enable the user to make data requests and receive the export efficiently, without unreasonable burden. For example, the health IT developer should not: Require the user to make a request multiple times for different types of EHI; provide unreasonable delays for the export; or prohibit reasonable user access to the system during the export process.

''Timely'' does not mean real-time; however, we stress that any delays in providing the export must be no longer than reasonably necessary to avoid interference with other clinical functions of the health IT system. This is similar to the approach we have taken for export of clinical quality measure data. The export capability does not require that data be received instantaneously. Rather, as we have stated before (80 FR 62650) a non-conformity would exist if surveillance revealed that processing or other delays were likely to substantially interfere with the ability of a provider or health system to view and verify their CQM results for quality improvement on a near real-time basis. Similarly, a non-conformity would exist if delays were causing or contributing to users being presented with data files that no longer contained current, accurate, or valid data. To avoid these implementation issues and ensure that capabilities support all required outcomes, health IT developers should seek to minimize processing times and other delays to the greatest extent possible.[26]

As previously defined under the Program, ''user'' is a health care professional or his or her office staff; or a software program or service that would interact directly with the certified health IT (80 FR 62611, 77 FR 54168). We typically would expect the ''user'' in this case to be a provider or his or her office staff who will be performing the request on behalf of the patient given that a request of this nature would likely occur in the context of an individual exercising their right of access under the HIPAA Privacy Rule (45 CFR 164.524). In this regard, the proposed 2015 Edition ''EHI export'' criterion could facilitate and support the provision of a patient's record in an electronic format. In service to innovative and patient-centric approaches, a health IT developer could develop a method that allows the patient using a technology application (*e.g.,* portal or ''app'') to execute the request without needing a provider to do so on their behalf. We seek comment on whether this portion of the criterion should be made more prescriptive to *only* allow the patient and his or her authorized representative to be the requestor of their EHI, similar to how we have previously scoped such criteria as ''view, download, and transmit to 3rd party'' (§ 170.315(e)(1)).

Similar to the 2015 Edition ''data export'' certification criterion (§ 170.315(b)(6)), which we propose for removal below, we acknowledge potential privacy and security concerns may arise when EHI is exported and, therefore, propose that for provider-mediated requests, a developer may design the health IT to limit the type of users that would be able to access and initiate EHI export functions. However, as we previously specified in the 2015 Edition final rule, the ability to ''limit'' the single patient EHI export functionality is intended to be used by and at the discretion of the provider organization implementing the technology, not a way for health IT developers to implicitly prevent the overarching user-driven aspect of this capability (80 FR 62646).

b. Transitions Between Health IT Systems

In addition to and separate from the patient access use case described above, health IT certified to this criterion would facilitate the migration of EHI to another health IT system. We propose that a health IT developer of health IT certified to this criterion must, at a customer's request, provide a complete export of all EHI that is produced or managed by means of the developer's certified health IT. Health IT developers would have flexibility as to how this outcome is achieved, so long as a customer is able to receive the export in a timely and efficient manner, and in a format that is commercially reasonable. For example, in contrast with the patient export capability, which must be available to a user without subsequent

[26] *https://www.healthit.gov/test-method/clinical-quality-measures-cqms-record-and-export#ccg.*

developer assistance to operate, the ''database export'' capability of this criterion could require action or support on the part of the health IT developer.

We note that while this criterion focuses on the technical outcomes supported by this capability, developers of health IT certified to this criterion would be required to provide the assurances proposed in § 170.402, which include providing reasonable cooperation and assistance to other persons (including customers, users, and third-party developers) to enable the use of interoperable products and services. Thus, while developers would have flexibility as to how they implement the export functionality for transitions between systems, they would ultimately be responsible for ensuring that the capability is deployed in a way that enables a customer and their third-party contractors to successfully migrate data. Such cooperation and assistance could include, for example, assisting a customer's third-party developer to automate the export of EHI to other systems. We refer readers to section VII.B.2 of the proposed rule for further discussion of a health IT developer's assurances as proposed in § 170.402.

c. Scope of EHI

For both use cases supported by this criterion, EHI export encompasses all the EHI that the health IT system produces and electronically manages for a patient or group of patients. This applies to the health IT's entire database, including but not limited to clinical, administrative, and claims/billing data. It would also include any data that may be stored in separate data warehouses that the system has access to, can produce, and electronically manages. For example, health IT developers may store EHI in these warehouses to prevent performance impacts from data queries that may slow down the ''main'' health IT system's (*e.g.,* EHR) clinical performance. We clarify that ''EHI'' also includes the oldest EHI available on that patient to the most recent, no matter the specific electronic format (*e.g.,* PDFs are included). As mentioned above, our intention is that ''produces and electronically manages'' refers to a health IT product's entire database. However, we seek comment on the terminology used (''produces and electronically manages'') and whether that captures our intent or whether there are any alternatives to the language we should consider to further clarify our intent. Alternative language we considered included ''produce and electronically retain'' data, which could encompass more data.

The use of the term ''electronic health information'' (EHI) is deliberate and in alignment with the Cures Act and the proposed definition of this term in § 170.102. Its use supports consistency and the breadth of types of data envisioned by this criterion. Clinical data would encompass imaging information—both images and narrative text about the image—as this is part of the patient's total record; however, we understand that EHRs may not be the standard storage location for images and solicit comment on the feasibility, practicality, and necessity of exporting images and/or imaging information. We request comment on what image elements, at a minimum, should be shared such as image quality, type, and narrative text. It is understandable that developers will not be able to export every existing data element, nor that all possible data elements are necessary for transfer. For finalization in a subsequent final rule, we solicit comment on whether we should require, to support transparency, health IT developers to attest or publish as part of the export format documentation the types of EHI they cannot support for export.

We also propose the following metadata categories that would be excluded from this criterion, and have listed examples for clarity below. We seek comment on these exclusion categories, and request feedback on what metadata elements should remain included for export, or be added to the list of data that would be allowed to be excluded in a subsequent final rule:

- Metadata present in internal databases used for physically storing the data. Examples include: Internal database table names, field names, schema, constraints, Triggers, Field size (number of bytes), Field type (String, integer, double, long), and Primary keys or object identifiers used internally for querying.
- Metadata that may not be necessary to interpret EHI export, including information that is typically required for processing of transactions such as encryption keys, internal user roles, ancillary information such as information stored in different formats, local codes for internal use; audit logs, record reviews, or history of change.
- Metadata that refers to data that is not present in the EHI export, such as links to files and other external attachments that are not part of the export, and information used in conjunction with data from other applications that is not part of the health IT.

We also seek comment, for consideration in finalizing this criterion in a subsequent final rule, on types of EHI that may present challenges for meeting the intent of this proposed criterion.

d. Export Format

The proposed certification criterion does not prescribe a content standard for the EHI export. However, it requires health IT developers to provide the format, such as a data dictionary or export support file, for the exported information to assist the receiving system in processing the EHI without loss of information or its meaning to the extent reasonably practicable using the developer's existing technology. Providing EHI export information is consistent with emerging industry practices and capabilities to offer requestors the ability to access, download, and move their information without unreasonable burden. Companies such as Facebook,[27] Google,[28] and Twitter[29] offer publicly-available links which provide requestors necessary information on how to download their personal information including, in some cases, several download options for requestors alongside their export instructions. Public access to comparable EHI export information would further support third-party companies in this space, as they would have additional information and general knowledge for use of available data. Accordingly, we propose that the developer's export format should be made publicly available via a hyperlink as part of certification to the ''EHI export'' criterion, including keeping the hyperlink up-to-date with the current export format.

We believe that by making the export format publicly available at the time of certification (and keeping the information current) will stimulate a vibrant, competitive market in which third- party software developers can specialize in processing the data exported from certified health IT products in support of patients and providers. Moreover, we believe this proposal will transform today's current guess-work, one-off processes into something more predictable and transparent such that greater industry efficiencies can be realized. We note and clarify that the export format need not be the same format used internally by the health IT system, and the health IT developer would not need to make public their proprietary data model. The proposed certification criterion also

[27] *https://www.facebook.com/help/1701730696756992?helpref=hc_global_nav.*

[28] *https://support.google.com/accounts/answer/3024190?hl=en.*

[29] *https://help.twitter.com/en/managing-your-account/how-to-download-your-twitter-archive.*

does not prescribe how the exported EHI is made available to the user, as this may depend on the size and type of information. We would expect that the information be made available to the user or requestor in an acceptable manner without placing unreasonable burden on the user or requestor. Please also generally see our discussion of information blocking in section VIII and particularly section VIII.D.5.

e. Initial Step To Persistent Access to All of a Patient's EHI

We believe that open, standards-based APIs should provide persistent access to patients' EHI over time to achieve the envisioned goals in § 170.404. In the meantime, this proposed criterion in § 170.315(b)(10) will provide an initial step toward achieving those goals. We clarify that ''persistent'' or ''continuous'' access to EHI is not required to satisfy this criterion's requirements and that the minimum requirement is for a discrete data export capability. Similarly, while the criterion requires the timely export of all EHI, such export need not occur instantaneously (or in ''real-time''). However, health IT developers are encouraged to consider persistent access and real-time approaches as part of the step-wise progression we see towards open, standards-based APIs for a growing number of data elements per the USCDI in the proposed ''standardized API for patient and population services'' criterion (§ 170.315(g)(10).'' Further, we caution that where it is reasonable for a developer to provide persistent or real-time access to electronic health information, the refusal to do so may be inconsistent with the Conditions of Certification in § 170.401 (information blocking) and § 170.402 (assurances related to this capability), as well as the information blocking provision, as to which readers should refer to sections VII and VIII of this proposed rule. Similarly, while this certification criterion would provide a baseline capability for exporting data for the specific use cases described above, health IT developers may need to provide other data export and conversion services or support additional export use cases beyond those encompassed by this criterion to facilitate the appropriate access, exchange, and use of electronic health information and to avoid engaging in information blocking.

f. Timeframes

ONC seeks input on EHI export and timeframes. In particular, beyond exporting *all* the EHI the health IT system produces and electronically manages, should this criterion include capabilities to permit health care providers to set timeframes for EHI export, such as only the ''past two years'' or ''past month'' of EHI?

For discussion of the required timeframe for developers of certified health IT *to certify to this proposed criterion and make it available to their customers,* please see Section VII.B.2, which addresses a health IT developer's required assurances regarding the availability and provision of this EHI export capability to its customers.

g. Replaces the 2015 Edition ''Data Export'' Criterion in the 2015 Edition Base EHR Definition

We propose to remove the ''data export'' criterion (§ 170.315(b)(6)) from the 2015 Edition, including the 2015 Edition Base EHR definition expressed in § 170.102. Correspondingly, we propose to include the proposed ''EHI export'' criterion (§ 170.315(b)(10)) in the 2015 Edition Base EHR definition, which would affect health care providers' compliance responsibilities when it comes to possessing CEHRT for associated CMS programs. A specific C–CDA data export criterion no longer supports advancements in interoperability in the evolving health IT industry. The proposed ''EHI export'' certification criterion is standards-agnostic and supports a more open approach to interoperability. More specifically, the proposed ''EHI export'' criterion differs significantly from the ''data export'' certification criterion as the latter is limited to clinical data as specified in the C–CDA. Also, the proposed ''EHI export'' criterion is not limited to just the scope of the certified capabilities in the certified Health IT Module as it applies to all produced and electronically managed EHI. Further, by including this functionality in the 2015 Base EHR definition, we can be assured that health care providers participating in the CMS programs (*e.g.,* Promoting Interoperability Programs) have functionality to both support patient requests for their EHI and switching health IT systems.

We propose to modify the Base EHR definition to include the proposed ''EHI export'' criterion 24 months from the effective date of the final rule for this proposed rule (which practically speaking would be 25 months because of the 30-day delayed effective date). We believe this is sufficient time for health IT developers to develop, test, certify, and rollout this functionality to health care providers based on the flexible approach offered for meeting this criterion. We also believe this timeframe provides sufficient time for health care providers to adopt and implement the functionality included in the ''EHI export'' criterion. To note, we refer readers to the ''Assurances'' Condition and Maintenance of Certification requirements in section VII.B.2, which propose complementary requirements on health IT developers to rollout health IT certified ''EHI export'' within 24 months of the effective date of a final rule for this proposed rule. We welcome comments on our proposed compliance timeline.

We note that we do not propose a transition period for the ''data export'' criterion. We propose to remove the criterion from the 2015 Edition upon the effective date of a final rule for this proposed rule. Unlike the ''application access—data category request'' criterion (which we propose to replace with the new API criterion in this proposed rule), the ''data export'' criterion does not support an objective or measure under the CMS Promoting Interoperability Programs. Therefore, we do not believe that health IT developers and health care providers need to support the functionality in the ''data export'' criterion while they transition to the development, adoption, and implementation of the EHI export criterion. This approach should reduce burden and costs for both health IT developers and health care providers. We welcome comments on this approach, including whether this will leave health care providers without an export capability for an inordinate period of time such that we should require health IT developers to support the ''data export'' functionality for health care providers until the health IT developer attests to providing the new EHI export functionality to all of its customers.

Readers are also referred to the Regulatory Impact Analysis in section XIV of this proposed rule for a discussion of the estimated costs and benefits of this proposed criterion, as well as the impact of the proposed removal of the 2015 Edition ''data export'' criterion.

5. Standardized API for Patient and Population Services Criterion

To implement the Cures Act, we propose to adopt a new API criterion in § 170.315(g)(10), which would replace the ''application access—data category request'' certification criterion (§ 170.315(g)(8)) and become part of the 2015 Edition Base EHR definition. This new certification criterion would require the use of FHIR standards, several implementation specifications, and focus on supporting two types of API-enabled services: (1) Services for

which a single patient's data is at focus; and (2) services for which multiple patients' data are at focus. Please refer to the ''Application Programming Interfaces'' section (VII.B.4) in this preamble for a more detailed discussion of the ''API'' certification criterion and related Conditions and Maintenance of Certification requirements.

6. Privacy and Security Transparency Attestations

a. Background

In 2015, the HIT Standards Committee (HITSC) recommended the adoption of two new certification criteria for the Program. The National Coordinator endorsed the HITSC recommendations for consideration by the Secretary, and the Secretary determined that it was appropriate to propose adoption of the two new certification criteria through rulemaking (81 FR 10635). To implement the Secretary's determination, we propose to add two new 2015 Edition privacy and security ''transparency attestation'' certification criteria for: (1) Encrypt authentication credentials; and (2) multi-factor authentication.

In the 2015 Edition final rule, we adopted a new, simpler, and straightforward approach to privacy and security (P&S) certification requirements for Health IT Modules certified to the 2015 Edition, which we refer to as the 2015 Edition privacy and security certification framework (80 FR 62705). In this proposed rule, we propose modifications to the 2015 Edition privacy and security certification framework in § 170.550(h) and propose to add new criteria to which a health IT developer would need to certify pertaining to whether or not its product encrypts authentication credentials (specifically § 170.315(d)(12)) and supports multi-factor authentication (specifically § 170.315(d)(13)). To be clear, we are not proposing to require that health IT *have* the functionality present to encrypt authentication credentials or support multi-factor authentication. Rather, we propose that a health IT developer indicate whether or not their certified health IT has those capabilities by attesting yes or no.

b. Encrypt Authentication Credentials

We propose to adopt an ''encrypt authentication credentials'' certification criterion in § 170.315(d)(12) and include it in the P&S certification framework (§ 170.550(h)). We propose to make the encrypt authentication credentials certification criterion applicable to any Health IT Module currently certified to the 2015 Edition and any Health IT Module presented for certification due to the fact that all health IT must meet the ''authentication, access control, and authorization'' certification criterion adopted in § 170.315(d)(1) as part of current Program requirements. While the 2015 Edition ''authentication, access control, and authorization'' certification criterion criteria requires that patient information saved on end user devices is encrypted, those same protections are not explicitly required through certification for the authentication credentials used to access that same information. As such, we believe that this proposal would address that gap and encourage health IT developers to take steps to ensure that authentication credentials are protected consistent with industry best practices.

To provide clarity as to what a ''yes'' attestation for ''encrypt authentication credentials'' would mean, we provide the following explanation. Encrypting authentication credentials could include password encryption or cryptographic hashing, which is storing only encrypted or cryptographically hashed passwords. If a developer attests that its Health IT Module encrypts authentication credentials, we propose that the attestation would mean that the Health IT Module is capable of cryptographically protecting stored authentication credentials in accordance with standards adopted in § 170.210(a)(2), Annex A: Federal Information Processing Standards (FIPS) Publication 140–2, Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules. We posit that FIPS Publication 140–2 is the seminal, comprehensive, and most appropriate standard. Moreover, in the specified FIPS 140–2 standard, there is an allowance for various approved encryption methods, and health IT developers would have the flexibility to implement any of the approved encryption methods in order to attest yes to this criterion. Health IT developers should keep apprised of these standards as they evolve and are updated to address vulnerabilities identified in the current standard.

We do not believe it is necessary for a Health IT Module to be required to be tested to this criterion, so long as by attesting yes to this criterion, the health IT developer is attesting that if authentication credentials are stored, then the authentication credentials are protected consistent with the requirements above. To be clear, a ''no'' attestation is a sufficient response to address this certification criterion; however, health IT developers should be aware that this ''no'' will be made publicly available on the CHPL. Note that if a developer attested to encrypting authentication credentials, a certified Health IT Module would be subject to ONC–ACB surveillance for any potential non-conformity with the requirements of this criterion. Specifically, if the ONC–ACB becomes aware of situations where the developer's health IT is not meeting the developer's affirmative attestation per the criterion's requirements, the ONC–ACB may use its corrective action process to bring the product back into conformance.

We propose that, for health IT certified prior to a subsequent final rule's effective date, the health IT would need to be certified to the ''encrypt authentication credentials'' certification criterion within six months after the final rule's effective date. For health IT certified for the first time after the final rule's effective date, we propose that the health IT must meet this criterion at the time of certification. This should allow sufficient time for health IT developers to assess their Health IT Modules' capabilities and attest ''yes'' or ''no'' to the certification criterion.

For an assessment of this proposal's costs and benefits, please refer to the Regulatory Impact Analysis in section XIV of this preamble. We welcome comments on this assessment and this proposal in general. We also note that some health IT presented for certification is not designed to store authentication credentials. Therefore, we specifically request comment on whether we should include an explicit provision in this criterion to accommodate such health IT. This could be similar to the approach we have taken with the 2015 Edition ''end-user device encryption'' criterion (§ 170.315(d)(7)(ii)), where we permit the criterion to be met if the health IT developer indicates their technology is designed to prevent electronic health information from being locally stored on end-user devices.

c. Multi-Factor Authentication

We propose to adopt a ''multi-factor authentication'' (MFA) criterion in § 170.315(d)(13) and include it in the P&S certification framework (§ 170.550(h)). We propose to make the ''multi-factor authentication'' certification criterion applicable to any Health IT Module currently certified to the 2015 Edition and any Health IT Module presented for certification. Health IT developers have already been implementing MFA to meet the Electronic Prescribing of Controlled Substances (EPCS) requirements set by Drug Enforcement Administration (DEA), and if adopted, this certification criterion would be general in that its

intended outcome would provide more public transparency around the MFA capabilities included in certified health IT.

This proposal supports the Department of Homeland Security (DHS) led initiative ''STOP, THINK, CONNECT'' which strongly recommends and runs campaigns to promote stronger authentication, typically related to MFA, going beyond a username and password to log in. MFA is also recommended by numerous organizations and groups. In the ''Report on Improving Cybersecurity in the Health Care Industry,'' [30] the Health Care Industry Cybersecurity Task Force recommended requiring strong authentication to improve identity and access management for health care workers, patients, and medical devices/EHRs. Using a single factor approach to accessing information is particularly prone to cyber-attack because one factor passwords can be weak, stolen, and are vulnerable to external phishing attacks, malware, and social engineering threats. In situations where the provider is accessing a health IT product or health information exchange external to the hospital or clinical environment, the Health Care Industry Cybersecurity Task Force recommended that the health care industry adopt the NIST SP 800–46 guidelines for remote access, including the use of two-factor authentication to ensure a compromised password cannot alone be used to gain access. Promoting the use of MFA and leveraging biometrics, mobile phones, and/or wearables can help to establish a trust relationship with the patient. Additionally, NIST recommends any personal data, whether self-asserted or validated, require MFA.

However, despite the benefits of adopting MFA, we are also aware of some of the challenges. Specifically, in health care, many providers are resistant to adopt MFA because of the inconvenience and loss of time of going through another step to access the patient's EHI. Also, MFA has not been deployed very long in the health care setting, so it is not clear how much it actually addresses the risk. In most MFA implementations, passwords are still present. In addition to having to manage passwords, users also have to manage an additional layer of security. Another usability challenge is that systems often require different types of MFA, which adds to the complexity and also may require providers to keep track of tokens. MFA is often recommended as a solution to password problems, but it is still vulnerable to theft. These alternative forms of authentication have their own set of vulnerability issues. The cost of implementing MFA and ensuring it will be implemented in a way that does not inhibit clinical workflow is also an issue to be considered.

To provide clarity as to what a ''yes'' attestation for ''multi-factor authentication'' attestation would mean, we provide the following explanation. MFA requires users to authenticate using multiple means to confirm they are who they claim to be in order to prove one's identity, under the assumption that it is unlikely that an unauthorized individual or entity will be able to succeed when more than one token is required. MFA includes using two or more of these: (i) Something people know, such as a password or a personal identification number (PIN); (ii) something people have, such as a phone, badge, card, RSA token or access key; and (iii) something people are, such as fingerprints, retina scan, heartbeat, and other biometric information. Thus, in order to be issued a certification, we propose to require that a Health IT Module developer attest to whether or not its certified health IT supports MFA consistent with industry recognized standards (*e.g.,* NIST Special Publication 800–63B Digital Authentication Guidelines, ISO 27001).

We propose that, for health IT certified prior to a subsequent final rule's effective date, the health IT would need to be certified to the ''multi-factor authentication'' certification criterion within six months after the final rule's effective date. For health IT certified for the first time after the final rule's effective date, we propose that the health IT must meet this criterion at the time of certification. This should allow sufficient time for health IT developers to assess their Health IT Modules' capabilities and attest ''yes'' or ''no'' to the certification criterion.

We generally seek comment on whether there is value in adopting the proposed ''multi- factor authentication'' criterion. We also solicit comment on the method of attestation and, if the health IT developer does attest to supporting MFA, whether we should require the health IT developer to explain how they support MFA. For example, should the health IT developer be required to identify the MFA technique(s) used/supported by submitting specific information on how it is implemented, including identifying the purpose(s)/use(s) to which MFA is applied within their Health IT Module (such as where in the clinical workflow it is required), and, as applicable, whether the MFA solution complies with industry standard? This information could enable the health IT developer to highlight their health IT's capabilities to support MFA.

7. Data Segmentation for Privacy and Consent Management Criteria

We adopted two 2015 Edition ''data segmentation for privacy'' (DS4P) certification criteria in the 2015 Edition final rule. One criterion (''DS4P-send'' (§ 170.315(b)(7)) includes capabilities for creating a summary care record formatted to the C–CDA 2.1 standard and document-level tagging as restricted (and subject to restrictions on re-disclosure) according to the DS4P standard. The other criterion (''DS4P-receive'' (§ 170.315(b)(8)) includes capabilities for receiving a summary care record formatted to the C–CDA 2.1 standard and document-level tagged as restricted (and subject to restrictions on re-disclosure) according to the DS4P standard. As noted in the 2015 Edition final rule (80 FR 62646)), certification to these criteria is not required to meet the CEHRT definition for CMS EHR Incentive Programs, now referred to as the Promoting Interoperability Programs. The current 2015 Edition DS4P certification criteria specify the technical capabilities that the health IT must have to apply and recognize security labels in a summary document (C–CDA) such that the recipient of a summary document would be able to recognize the existence of sensitive elements within the summary document (80 FR 62646). Security labeling provides a way for computer systems to properly handle data passed among systems, to preserve the condition of security, and to enable access control decisions on the information, so that the information is only accessed by the appropriate entities. The HL7 Healthcare Classification System (HCS) standard provides a common syntax and semantics for interoperable security labels in health care. The DS4P standard makes use of the HCS specification and describes a method for applying security labels to HL7 CDA documents to ensure that privacy policies established at a record's source can be understood and enforced by the recipient of the record.

In the 2015 Edition final rule, we noted that the DS4P standard is not restricted to data subject to the federal regulations governing the Confidentiality of Substance Use Disorder Patient Records (42 CFR part 2) (80 FR 62647). It may be implemented to support other data exchange use cases in which compliance with state or federal legal frameworks require sensitive health information to be tagged

[30] *https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf.*

and segmented (80 FR 62647). We further stated that we offered certification to these criteria as an initial step towards the ability of an interoperable health care system to use technical standards to compute and persist security labels to permit access, use, or disclosure of protected health information in accordance with applicable policies and patient preferences. We understood and acknowledged additional challenges surrounding the prevalence of unstructured data, sensitive images, and potential issues around use of sensitive health information by clinical decision support systems. The adoption of document level data segmentation for structured documents would not solve these issues, but we acknowledged it would help move technology in the direction where these issues could be addressed (80 FR 16841).

Adoption of the current 2015 Edition DS4P criteria was also consistent with earlier HIT Policy Committee (HITPC) recommendations on the use of DS4P technology to enable the electronic implementation and management of disclosure policies that originate from the patient, the law, or an organization, in an interoperable manner, so that electronic sensitive health information may be appropriately shared.[31] These HITPC recommendations consisted of a glide path for the exchange of 42 CFR part 2-protected data starting with the inclusion of Level 1 (document level tagging) send and receive functionality. The HITPC also recommended advancing the exchange of 42 CFR part 2-protected data, by outlining additional capabilities in sharing, viewing and incorporating privacy restricted data at a more granular level, as well as managing computable patient consent for the use of restricted data.[32]

Since the 2015 Edition final rule, the health care industry has engaged in additional field testing and implementation of the DS4P standard. As of the beginning of the third quarter of the 2018 CY, only about 20 products (products with multiple certified versions were counted once) were certified to the current 2015 Edition DS4P certification criteria. In addition, stakeholders shared with ONC—through public forums, listening sessions, and correspondence—that focusing certification on segmentation to only the document level does not permit providers the flexibility to address more granular segmentation needs. Stakeholders noted that certain provider types, such as providers of pediatric care and behavioral health care, are currently using a range of burdensome manual workflows in order to meet complex use cases for DS4P which are also impacted by state and local laws. Additionally, stakeholders have expressed interest in ONC exploring health IT standards that work with DS4P to support the management of consent for sharing documents that include security labels such as through the use of an API.

Therefore, in consideration of stakeholder feedback and our stated policy approach to adopt DS4P certification criteria on a glide path, we propose to remove the current 2015 Edition DS4P-send (§ 170.315(b)(7)) and DS4P-receive (§ 170.315(b)(8)) certification criteria. The proposed effective date of removal of these criteria would be the effective date of a subsequent final rule for this proposed rule. We propose to replace these two criteria with three new 2015 Edition DS4P certification criteria (two for C–CDA and one for a FHIR-based API) that would support a more granular approach to privacy tagging data and consent management for health information exchange supported by either the C–CDA– or FHIR-based exchange standards. Our primary purpose for proposing to remove and replace them, in lieu of proposing to revise them, is to provide clarity to stakeholders as to the additional functionality enabled by health IT certified to the new criteria. We note resources released by ONC and OCR, such as the HHS Security Risk Assessment Tool[33] and the Guide to Privacy and Security of Electronic Health Information,[34] as well as the Office for Civil Rights' security risk analysis guidance[35] that entities may employ to make risk-based decisions regarding their implementation of the proposed DS4P criteria. We also note the availability of the Electronic Consent Management Landscape Assessment, Challenges, and Technology report.[36] The report includes suggestions for overcoming barriers associated with implementing electronic consent management, which may be considered for further research and discussion.

a. Implementation With the Consolidated CDA Release 2.1

In place of the removed 2015 Edition DS4P criteria, we propose to adopt new DS4P-send (§ 170.315(b)(12)) and DS4P-receive (§ 170.315(b)(13)) criteria that would remain based on the C–CDA and the HL7 DS4P standard. These criteria would include capabilities for applying the DS4P standard at the document, section, and entry level. We believe this offers more valuable functionality to providers and patients, especially given the complexities of the landscape of privacy laws for multiple care and specialty settings. We believe health IT certified to these criteria could support multiple practice settings and use cases. For example, in section VI.A.2 of this preamble, we explain how the proposed capabilities included in these criteria could support the pediatric health care setting. We believe this proposal could also reduce burden for providers by leveraging health IT's ability to recognize and manage sensitive data and patient consent directives, rather than relying on case-by-case manual redaction and subsequent workarounds to transmit redacted documents. We emphasize that health care providers already have processes and workflows to address their existing compliance obligations which could be made more efficient and cost effective through the use of health IT. We recognize that more granular privacy markings at the point of data capture would further support existing and future priorities of states for multiple care and specialty settings, including behavioral health and pediatric health care settings.

We welcome public comment on our proposals to replace the current 2015 Edition DS4P criteria and adopt new 2015 Edition DS4P-send (§ 170.315(b)(12)) and DS4P-receive (§ 170.315(b)(13)) criteria to support improved options for data segmentation for health care providers engaged in complex use cases such as those identified in pediatric care (*see also* section VI.A) and behavioral health

[31] See HIT Policy Committee (HITPC) Recommendation Letter to ONC, July 2014, *http://www.healthit.gov/facas/sites/faca/files/PSTT_DS4P_Transmittal%20Letter_2014-07-03.pdf;* see also HITPC's Privacy and Security Tiger Team Public Meeting, Transcript, May 12, 2014, *http://www.healthit.gov/facas/sites/faca/files/PSTT_Transcript_Final_2014-05-12.pdf;* Public Meeting, Transcript, May 27, 2014, *http://www.healthit.gov/facas/sites/faca/files/PSTT_Transcript_Final_2014-05-27.pdf.*

[32] For more details on the two glide paths for part 2-protected data, see *http://www.healthit.gov/facas/sites/faca/files/PSTT_DS4P_Transmittal%20Letter_2014-07-03.pdf.*

[33] HHS Security Risk Assessment Tool: *http://www.healthit.gov/providers-professionals/security-risk-assessment.*

[34] ONC Guide to Privacy and Security of Electronic Health Information: *http://www.healthit.gov/sites/default/files/ pdf/privacy/privacy-and-security-guide.pdf.*

[35] HHS Office for Civil Rights:*https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html;* and *https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html?language=es.*

[36] *https://www.healthit.gov/sites/default/files/privacy-security/ecm_finalreport_forrelease62415.pdf.*

care, including for opioid use disorder (OUD) (*see also* section VI.B).

b. Implementation With FHIR Standard

In collaboration with ONC, the Substance Abuse and Mental Health Services Administration (SAMHSA) developed the Consent2Share application to address the specific privacy protections of patients with substance use disorders who are covered by the federal confidentiality regulation, 42 CFR part 2. Consent2Share is an open source application for data segmentation and consent management. It is designed to integrate with existing FHIR systems. SAMHSA created a FHIR implementation guide (the Consent2Share Consent Profile Design, hereafter referred to as ''Consent Implementation Guide'') that describes how the Consent2Share (C2S) application and associated access control solution uses the FHIR Consent resource to represent and persist patient consent for treatment, research, or disclosure.[37] The implementation guide provides instructions for using the FHIR Consent resource to capture a record of a health care consumer's privacy preferences.

As discussed in section VII.B.4 of this proposed rule, we are proposing policies related to the implementation of a standardized API to support the exchange of health information between providers and patients and among members of a care team. We anticipate that the proposed 2015 Edition ''standardized API for patient and population services'' certification criterion (§ 170.315(g)(10)) will result in a proliferation of APIs that will enable a more flexible and less burdensome approach to exchanging EHI. We believe the health care industry can leverage this API infrastructure to share segmented data in a secure and scalable manner. Therefore, we propose to adopt a 2015 Edition certification criterion ''consent management for APIs'' in § 170.315(g)(11) to support data segmentation and consent management through an API in accordance with the Consent Implementation Guide. Certification to this criterion would be at a health IT developer's discretion and would indicate that a system is capable of responding to requests through an API for patient consent directives that include standards-based security labeling.

We acknowledge that our proposed implementation specification, the Consent Implementation Guide, is based on a different version of the FHIR standard (FHIR Standard for Trial Use 3, also known as FHIR Release 3) than the proposed ''standardized API for patient and population services'' criteria (§ 170.315(g)(10)) which is proposed to reference just FHIR Release 2. Furthermore, we acknowledge that this discrepancy may result in additional implementation efforts for developers. In ideal circumstances, we would have proposed a data segmentation and consent management standard for APIs that was based on FHIR Release 2 and aligned with the ''standardized API for patient and population services'' criteria proposed in this proposed rule. However, although SAMHSA also created a consent implementation guide based on FHIR Release 2,[38] the guide used the FHIR ''Contract'' resource to represent patient consent directives. It is our understanding that an approach based on the ''Contract'' resource has since been abandoned by the industry in favor of using the ''Consent'' resource which was introduced in FHIR Release 3. Moreover, the FHIR Release 2 version of the Consent Implementation Guide went through relatively little testing and was never formally implemented because SAMHSA began developing an update to the guide based on the ''Consent'' resource in FHIR Release 3. Consequently, proposing an implementation specification based on FHIR Release 2 would not have aligned with the more common implementation of FHIR-based consent directives by the health care industry. We do not anticipate that the initial misalignment between the proposed API criterion (§ 170.315(g)(10)) and the proposed third DS4P criterion (§ 170.315(g)(11)) will pose a significant burden on health IT developers. Further, our proposal to permit health IT developers to voluntarily implement and use a new version of an adopted standard or implementation specification so long as such version was approved by the National Coordinator for use in certification through the Standards Version Advancement Process, discussed in section VII.B.5, would enable standards version alignment between these two criteria in the future as the FHIR standard matures.

SAMHSA created the ''Consent Implementation Guide'' to support developers in implementing the FHIR Consent resource to represent patient consent for treatment, research, and disclosure. The Consent Implementation Guide provides instructions for using the FHIR ''Consent'' resource to capture a record of a health care consumer's privacy preferences. Implementing an instance of the FHIR Consent resource based on this guide allows for a patient consent to permit or deny identified recipient(s) or recipient role(s) to perform one or more actions, regarding the patient's health information for specific purposes and periods of time. For example the Consent Implementation Guide supports consent management for specific use cases to permit or deny disclosure based on a specific law, regulation, or policy under which the patient consented. The implementation guide uses security labels as a mechanism for specifying a patient's preferences (*e.g.,* permit disclosure of EHI labeled ''restricted''). The Consent Implementation Guide provides a much simpler mechanism for representing a patient's consent preferences than the old approach based on FHIR Release 2 and has undergone implementation and pilot testing by SAMHSA's Consent2Share (C2S) application.

Our proposal to adopt the version aligned with FHIR Release 3 and the FHIR Release 3 standard for this criterion reflects stakeholder interests and efforts to support particular use cases. C2S enables data segmentation and consent management for disclosure of several discrete categories of sensitive health data related to conditions and treatments including: Alcohol, tobacco and substance use disorders (including opioid use disorder), behavioral health, HIV/AIDS, and sexuality and reproductive health. These capabilities support multiple use cases in both primary and specialty care, and specifically address priority needs identified by stakeholders to support pediatric care. We emphasize that health care providers already have processes and workflows to address their existing compliance obligations which could be made more efficient and cost effective through the use of health IT. Finally, given that the FHIR standard is modular in nature, and especially since the ''Consent'' resource did not exist in FHIR Release 2, we anticipate that health IT developers that elect to certify to this criterion would be able to support the Consent Implementation Guide along with the API requirements specified in ''standardized API for

[37] The draft FHIR IG titled ''*Consent2Share FHIR Profile Design.docx*'' can be accessed through the Community- Based Care and Privacy (CBCP) HL7 workgroup, within the Package Name titled ''*BHITS_FHIR_Consent_IG,*'' at *https://gforge.hl7.org/gf/project/cbcc/frs/.*

[38] The draft Behavioral Health Information Technologies and Standards (BHITS) FHIR DSTU2 Consent Implementation Guide can be accessed through the Community-Based Care and Privacy (CBCP) HL7 workgroup at *https://gforge.hl7.org/gf/project/cbcc/frs/?action=FrsReleaseView&release_id=1279.*

patient and population services'' (§ 170.315(g)(10)) with modest extra effort.

We welcome comments on this proposal. We specifically seek comment on how the availability of this proposed certification criterion might increase the ability to support multiple care coordination and privacy priorities, including those associated with pediatric care; and whether we should consider other similar API based options and resources as standards for certification criteria. We also seek comment on whether the misalignment between the versions of the FHIR standard used by our proposed ''consent management for APIs'' and ''standardized API for patient and population services'' criteria would create excessive burden for developers and implementers. Specifically, we seek comment on if certification to the ''consent management for APIs'' should only be available in conjunction with the ''standardized API for patient and population services'' criteria at such a time as the criteria are aligned to one version of the FHIR standard or if the option to certify to the ''consent management for APIs'' should be allowed for those developers interested in doing so even without current standards alignment. We note that SAMHSA is currently pursuing additional work to expand use cases related to data segmentation for privacy and FHIR compatibility.

C. Unchanged 2015 Edition Criteria—Program Reference Alignment

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20516), CMS proposed scoring and measurement policies to move beyond the three stages of meaningful use to a new phase of EHR measurement with an increased focus on interoperability and improving patient access to health information. To reflect this focus, CMS changed the name of the Medicare and Medicaid EHR Incentive Programs, to the Medicare and Medicaid Promoting Interoperability (PI) Programs. To align with the renaming of the EHR Incentive Programs, we propose to remove references to the EHR Incentive Programs and replace them with ''Promoting Interoperability Programs'' in the 2015 Edition ''automated numerator recording'' criterion in § 170.315(g)(1) and the ''automated measure calculation'' criterion in § 170.315(g)(2).

V. Modifications to the ONC Health IT Certification Program

A. Corrections

1. Auditable Events and Tamper Resistance

Currently, § 170.315(d)(2), ''auditable events and tamper resistance,'' includes a cross- reference to § 170.315(d)(7). However, the cross reference to § 170.315(d)(7), ''end-user device encryption,'' does not always apply. We propose to revise § 170.550(h)(3) to apply the § 170.315(d)(7) cross reference as appropriate and exempt § 170.315(d)(7) when the certificate scope does not require § 170.315(d)(7) certification (*see* § 170.315(d)(2)(i)(C)). Paragraph 170.315(d)(2)(i)(C) is not applicable for the privacy and security testing and certification of a Health IT Module required by § 170.550(h)(3)(iii), (v), (vii), and (viii). This specific requirement was intended to be exempted. It would only apply if § 170.315(d)(7) was also required for privacy and security testing and certification, which it is not under the aforementioned paragraphs. For example, a developer that is seeking to certify a Health IT Module to § 170.315(h) will not necessarily have end-user device encryption features (*see* § 170.315(d)(7)). As such, certification can proceed for the audit log process without the Health IT Module demonstrating that it can record an encryption status as required by § 170.315(d)(2)(i)(C). We have previously identified this error in guidance and now propose to codify the correction in regulation.[39]

2. Amendments

We propose to revise § 170.550(h) to remove the ''amendments'' criterion's application to certain non-applicable clinical criteria including: ''Drug-drug, drug-allergy interaction checks for computerized provider order entry (CPOE)'' § 170.315(a)(4); ''clinical decision support'' § 170.315(a)(9); ''drug-formulary and preferred drug list checks'' § 170.315(a)(10); and ''patient-specific education'' § 170.315(a)(13). Health IT Modules presented for certification to these criteria would not have to demonstrate the capabilities required by the 2015 Edition ''amendments'' certification criterion (§ 170.315(d)(4)), unless the health IT is presented for certification to another criterion that requires certification to the 2015 Edition ''amendments'' criterion under the P&S certification framework. This has already been incorporated into sub- regulatory guidance, and we propose to codify this clarification in regulation.[40] The revision was made upon further analysis of the P&S certification framework and the applicability of the ''amendments'' certification criterion § 170.315(d)(4) to health IT capabilities that would not necessarily have any patient data for which a request for an amendment would be relevant.

3. View, Download, and Transmit to 3rd Party

We propose to remove § 170.315(e)(1)(ii)(B) which includes a cross-reference to § 170.315(d)(2). This cross-reference indicates that health IT may demonstrate compliance with activity history log requirements if it is also certified to the 2015 Edition ''auditable events and tamper-resistance'' certification criterion (§ 170.315(d)(2)). However, we no longer require testing of activity history log when certifying for § 170.315(d)(2). Therefore, this cross-reference is no longer applicable to meet certification requirements for the 2015 Edition ''view, download, and transmit to 3rd party'' certification criterion (§ 170.315(e)(1)) activity history log requirements.

4. Integrating Revised and New Certification Criteria Into the 2015 Edition Privacy and Security Certification Framework

Consistent with the 2015 Edition privacy and security certification framework, each certification criterion has a set of appropriate P&S ''safeguards'' that must be in place. In the 2015 Edition, we required that an ONC–ACB must ensure that a Health IT Module presented for certification to any of the certification criteria that fall into each regulatory text ''first level paragraph'' category of § 170.315 (*e.g.,* § 170.315(a)) identified below would be certified to either Approach 1 (technically demonstrate) or Approach 2 (system documentation). In this proposed rule, we propose to require the new criteria (§ 170.315(d)(12) and (d)(13)) to apply to all § 170.315 certification criteria. Therefore, given these and the other modifications discussed above, we propose to revise the P&S certification framework as

[39] *https://www.healthit.gov/sites/default/files/2015Ed_CCG_d2-Auditable-events-tamper-resistance.pdf.*

[40] *https://www.healthit.gov/sites/default/files/2015Ed_CCG_a4-DD-DAI-checks-for-CPOE.pdf, https://www.healthit.gov/sites/default/files/2015ed_ccg_a9-clinical-decision-support.pdf, https://www.healthit.gov/sites/default/files/2015Ed_CCG_a10-Drug-formulary-PDL-checks.pdf,* and *https://www.healthit.gov/sites/default/files/2015Ed_CCG_a13-Patient-specific-ed-resources.pdf.*

noted in the table below. However, the P&S Certification Framework would need to be further updated depending on finalization of the proposals discussed in section III.B.4, which propose removal of certain 2015 Edition certification criteria.

TABLE 1—PROPOSED 2015 EDITION PRIVACY AND SECURITY CERTIFICATION FRAMEWORK

If the Health IT Module includes capabilities for certification listed under:	It will need to be certified to approach 1 or approach 2 for each of the P&S certification criteria listed in the "approach 1" column	
	Approach 1	Approach 2
§ 170.315(a)(1), through (2), (5), through (8), (11), and (12).	§ 170.315(d)(1) (authentication, access control, and authorization), (d)(2) (auditable events and tamper resistance), (d)(3) (audit reports), (d)(4) (amendments), (d)(5) (automatic log-off), (d)(6) (emergency access), and (d)(7) (end-user device encryption).	For each applicable P&S certification criterion not certified using Approach 1, the health IT developer submits system documentation that is sufficiently detailed to enable integration such that the Health IT Module has implemented service interfaces for each applicable P&S certification criterion that enable the Health IT Module to access external services necessary to meet the requirements of the P&S certification criterion.
§ 170.315(a)(4), (9), (10), and (13).	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(7).	
§ 170.315(b)	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8) (integrity).	
§ 170.315(c)	§ 170.315(d)(1) through (d)(3) and (d)(5)*.	
§ 170.315(e)(1)	§ 170.315(d)(1) through (d)(3), (d)(5), (d)(7), and (d)(9)(trusted connection).	
§ 170.315(e)(2) and (3)	§ 170.315(d)(1) through (d)(3), (d)(5), and (d)(9)*.	
§ 170.315(f)	§ 170.315(d)(1) through (d)(3) and (d)(7).	
§ 170.315(g)(7) through (g)(11).	§ 170.315(d)(1) and (d)(9); and (d)(2) or (d)(10) (auditing actions on health information).	
§ 170.315(h)	§ 170.315(d)(1) through (d)(3)*.	
§ 170.315(b)	§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8) (integrity).	
§ 170.315(c)	§ 170.315(d)(1) through (d)(3) and (d)(5).	
§ 170.315(e)(1)	§ 170.315(d)(1) through (d)(3), (d)(5), (d)(7), and (d)(9)(trusted connection).	
§ 170.315(e)(2) and (3)	§ 170.315(d)(1) through (d)(3), (d)(5), and (d)(9).	

§ 170.315(a)–(h) Certification Criterion	
§ 170.315(a) through (h) Certification Criterion	§ 170.315(d)(12)
§ 170.315(a) through (h) Certification Criterion	§ 170.315(d)(13)

An ONC–ACB must ensure that a Health IT Module presented for certification to any of the certification criteria that fall into each regulatory text "first level paragraph" category of § 170.315 (e.g. § 170.315(a)) identified in the table above is certified to either Approach 1 (technically demonstrate) or Approach 2 (systemdocumentation). In addition, we propose that health IT developers seeking certification to any § 170.315 certification criterion for their Health IT Modules attest to whether they encrypt authentication credentials (§ 170.315(d)(12)) and support multi-factor authentication (§ 170.315(d)(13))

We clarify that of the adopted 2015 Edition certification criteria, only the privacy and security criteria specified in § 170.315(g)(1) through (6) are exempt from the 2015 Edition privacy and security certification framework due to the capabilities included in these criteria, which do not implicate privacy and security concerns.

In order to be issued a certification, a Health IT Module would only need to be tested once to each applicable privacy and security criterion identified as part of Approach 1 or Approach 2 so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification, except for the certification of a Health IT Module to § 170.315(e)(1) "view, download, and transmit to 3rd party" and (e)(2) "secure messaging." For each of these criteria, a Health IT Module must be separately tested to § 170.315(d)(9) because of the specific capabilities for secure electronic transmission and secure electronic messaging included in each criterion, respectively. We also propose the health IT developers seeking certification to any § 170.315 certification criterion for their Health IT Modules attest to whether they encrypt authentication credentials (§ 170.315(d)(12)) and support multi-factor authentication (§ 170.315(d)(13))

* § 170.315(d)(2)(i)(C) is not required if the scope of the Health IT Module does not have end-user device encryption features.

B. Principles of Proper Conduct for ONC–ACBs

1. Records Retention

We propose to revise the records retention requirement in § 170.523(g) to include the ''life of the edition'' as well as 3 years after the retirement of an edition related to the certification of Complete EHRs and Health IT Module(s). In the 2015 Edition final rule (80 FR 62602), we adopted a records retention provision that required ONC–ACBs to retain all records related to the certification of Complete EHRs and Health IT Module(s) for the ''life of the edition'' plus an additional 3 years, and the records would be available to HHS upon request during this period of time. In the 2015 Edition final rule, the ''life of the edition'' was defined as beginning with the codification of an edition of certification criteria in regulation and ending when the edition is removed from regulation. We now propose to clarify that HHS has the ability to access certification records for the ''life of the edition,'' which begins with the codification of an edition of certification criteria in the Code of Federal Regulations through a minimum of 3 years from the effective date that removes the applicable edition from the Code of Federal Regulations, not solely during the 3-year period after removal from the CFR.

2. Conformance Methods for Certification Criteria

The Principle of Proper Conduct (PoPC) in § 170.523(h) specifies that ONC–ACBs may only certify health IT that has been tested by ONC–ATLs using tools and test procedures approved by the National Coordinator. We propose to revise this PoPC in three ways. First, we propose to revise this PoPC to additionally permit ONC–ACBs to certify Health IT Modules that they have evaluated for conformance with certification criteria without first passing through an ONC–ATL. However, we propose that such methods to determine conformity must first be approved by the National Coordinator. This proposal provides valuable Program flexibility and market efficiencies for streamlining Health IT Module certification, acknowledging the broad spectrum of evidence of conformance, from laboratory testing with an ONC–ATL to developer self-declaration. This Program flexibility will also allow us to leverage the success we have seen in implementation of our alternative test method process where any entity can submit a test procedure and/or test tool for approval for use under the Program. For example, the National Coordinator may, under this provision, approve a conformance method for certification criteria where evidence of a valid declaration of conformity (*e.g.,* certification) granted under an external program can be submitted directly to an ONC–ACB to meet the requirement of that certification criteria.

Second, we propose to revise the PoPC to clarify that certifications can only be issued to Health IT Modules and not Complete EHRs. We are proposing to remove the 2014 Edition from the CFR (*see* section II.B.2 of this preamble) and Complete EHR certifications are no longer available for certification to the 2015 Edition (80 FR 62608; 79 FR 54443). We propose to remove the provision that permits the use of test results from National Voluntary Laboratory Accreditation Program (NVLAP)-accredited testing laboratories under the Program because the regulatory transition period from NVLAP-accredited testing laboratories to ONC–ATLs has expired (81 FR 72447).

Third, we propose to remove the provision that permits the certification of health IT previously certified to an edition if the certification criterion or criteria to which the Health IT Module(s) was previously certified have not been revised and no new certification criteria are applicable because the circumstances that this provision seeks to address are no longer feasible with certification to the 2015 Edition. Any Health IT Module previously certified to the 2014 Edition and presented for certification to the 2015 Edition would have at least one new or revised 2015 Edition certification criteria that would be applicable. For example, the 2015 Edition ''accessibility-centered design'' criterion (§ 170.315(g)(5)) is applicable to any Health IT Module presented for certification to the 2015 Edition.

3. ONC–ACBs To Accept Test Results From Any ONC–ATL in Good Standing

We propose to revise the PoPC for ONC–ACBs in order to address business relationships between ONC–ACBs and ONC–ATLs. To encourage market competition, we propose to require ONC–ACBs to accept test results from any ONC–ATL that is in good standing under the Program and is compliant with its ISO 17025 accreditation requirements. However, if an ONC–ACB has concerns about accepting test results from a certain ONC–ATL, the ONC–ACB would have an opportunity to explain the potential issues to ONC and NVLAP, and on a case-by-case basis, ONC could consider the facts and make the final determination.

ONC–ATLs must be accredited by the NVLAP and seek authorization from ONC to participate in the ONC Health IT Certification Program. ONC–ATLs test products against the ONC-approved test method for the standards and certification criteria identified by the Secretary using ONC-approved test methods. ONC–ACBs make certification determinations and conduct surveillance for health IT originally tested by an ONC–ATL. Based on the process that all ONC-ATLs must undergo, we believe that they are capable of providing accurate test results that should be accepted by any ONC–ACB.

The intent of this proposal is to ensure that ONC–ATLs are not discriminated against and do not suffer injury from ONC–ACBs not accepting their test results if, in fact, they are in good standing. This proposal may also prevent harm to health IT developers, who present their health IT to be tested by ONC–ATLs and ultimately seek certification by ONC–ACBs under the Program. These situations may arise if a health IT developer's ONC–ACB leaves the Program or goes out of business. This proposal may also prevent situations of preferential business arrangements such as when one organization is both an ONC–ATL and ONC–ACB and will not enter into a contract with another organization who is also an ONC–ATL.

4. Mandatory Disclosures and Certifications

We propose to revise the PoPC in § 170.523(k). We propose to remove § 170.523(k) (1)(ii)(B) because certifications can only be issued to Health IT Modules and not Complete EHRs. We are proposing to remove the 2014 Edition from the CFR (*see* section III.B.2 of this preamble) and Complete EHR certifications are no longer available for certification to the 2015 Edition (80 FR 62608; 79 FR 54443). We also propose to revise § 170.523(k)(1)(iii) to broaden the section beyond just the Medicare and Medicaid EHR Incentive Programs (now referred to as Promoting Interoperability Programs). We propose to revise the section to include a detailed description of all known material information concerning additional types of costs or fees that a user may be required to pay to implement or use the Health IT Module's capabilities, whether to meet provisions of HHS programs requiring the use of certified health IT or to achieve any other use within the scope of the health IT's certification.

We also propose to remove the provision in § 170.523(k)(3) that requires a certification issued to a pre-coordinated, integrated bundle of Health IT Modules to be treated the same as a certification issued to a Complete EHR for the purposes of § 170.523(k)(1), except that the certification must also indicate each Health IT Module that is included in the bundle. We propose to remove this provision because pre-coordinated, integrated bundles are no longer applicable for certification under Program.

We propose to revise § 170.523(k)(4) to clarify that a certification issued to a Health IT Module based solely on the applicable certification criteria adopted by the ONC Health IT Certification Program must be separate and distinct from any other certification(s) based on other criteria or requirements. The intent of this provision, as indicated in the Establishment of the Permanent Certification Program for Health Information Technology final rule (76 FR 1272), is to ensure that any other certifications an ONC–ACB may issue, is separately indicated from the applicable certification criteria adopted by the ONC Health IT Certification Program.

We also propose changes related to transparency attestations and limitations in section III.B.5. of this preamble. Additionally, we propose other new PoPCs for ONC–ACBs in sections VII.B.5 and VII.D of this preamble.

C. Principles of Proper Conduct for ONC–ATLs—Records Retention

We propose to revise the records retention requirement in § 170.524(f) to include the ''life of the edition'' as well as 3 years after the retirement of an edition related to the certification of Health IT Module(s). The circumstances are the same as in section V.B.1 of this preamble mentioned above, therefore, we propose the same revisions for ONC–ATLs as we did for ONC-ACBs.

VI. Health IT for the Care Continuum

ONC believes health IT should help promote and support patient care when and where it is needed. This means health IT should help support patient populations, specialized care, transitions of care, and practice settings across the care continuum. In the Permanent Certification Program final rule, we clarified that section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a voluntary certification program or programs for other types of health IT beyond those which supported the EHR Incentive Programs (now called the Promoting Interoperability Programs). However, we decided that the initial focus of the Program should be on supporting the EHR Incentive Programs, which focuses on EHR technology for the ambulatory and inpatient settings (76 FR 1294). As the Program evolved and the adoption and use of certified health IT increased significantly, we modified the Program in the 2015 Edition final rule to make it more open and accessible to more types of health IT, including health IT that supports various care and practice settings beyond those included in the EHR Incentive Programs (80 FR 62604). Our goal was then and is now to support the advancement of interoperable health IT and to promote health IT functionality in care and practice settings across the care continuum (*see also* 80 FR 62604).

ONC's efforts in the 2015 Edition to make the Program more open and accessible to other care settings also aligned with fall 2013 recommendations from the HIT Policy Committee (HITPC). The HITPC examined the extension of the Program to include functionalities that would benefit settings not covered by the EHR Incentive Programs. The HITPC recommended that considerations regarding functionality should focus on whether the functionality would:

- Advance a national priority or legislative mandate
- Align with existing federal/state programs
- Utilize the existing technology pipeline
- Build on existing stakeholder support
- Appropriately balance the costs and benefits of a certification program.

Taking into consideration the HITPC recommendations, ONC's 2015 Edition focused on the adoption of certification criteria that are standards-based, applicable to a wide variety of care and practice settings, and that advance the structured recording, access, exchange, and use of health information. ONC has also encouraged users—including specialty groups—to continue to work with developers to innovate, develop, and deploy health IT in specific clinical settings in ways that promote safety, effectiveness, and efficient health care delivery while also reducing burden.

In the 2015 Edition final rule we stated that we did not intend to develop and issue separate regulatory certification ''paths'' or ''tracks'' for particular care or practice settings (*e.g.,* a ''long-term and post-acute care (LTPAC) certification'') because it would be difficult to *independently* construct such ''paths'' or ''tracks'' in a manner that would align with other relevant programs and specific stakeholder needs. While we never have had intentions to adopt care- or practice-specific certification tracks, or additional voluntary program(s), in parallel to the existing voluntary ONC Health IT Certification Program, we stated that we would welcome the opportunity to work with HHS agencies, other agencies, and provider associations in identifying the appropriate functionality and certification criteria in the Program to support their stakeholders (80 FR 62704). This approach is consistent with the recommendations by the HITPC.

Since the publication of the 2015 Edition final rule, ONC has explored how we might work with the industry and with specialty organizations to collaboratively advance health IT that supports medical specialties and sites of service. As a result, we have gained insight from stakeholders regarding the burdens associated with establishing a specific set of required certification criteria for all users—which may include capabilities not applicable to certain settings of care or specialties. Stakeholders have also noted that the adoption of a set of required criteria without also enabling and incentivizing innovation beyond those criteria may have the unintended consequence of stifling progress for that setting. Stakeholders noted that the timeline for testing and certifying to required criteria and the subsequent deployment of certification criteria in practice settings is not always aligned with standards updates, the emergence of new standards, or technological innovation. Finally, stakeholders have urged ONC to leverage multiple means to advance interoperability standards that are widely applicable, to enable and promote innovation that is supported by these standards, and—in collaboration with stakeholders to monitor and support developments in emerging standards and technologies for specialty use cases.

Section 4001(b)(i) of the Cures Act instructs the National Coordinator to encourage, keep, or recognize, through existing authorities, the voluntary certification of health IT under the Program for use in medical specialties and sites of service for which no such technology is available or where more technological advancement or integration is needed. This provision of the Cures Act closely aligns with ONC's ongoing collaborative efforts with both federal partners and stakeholders within the health care and health IT community to encourage and support the advancement of health IT for a wide

range of clinical settings. These initiatives have included projects related to clinical priorities beyond those specifically included in the EHR Incentive Programs (now called the Promoting Interoperability Programs) including efforts in public health, behavioral health, and long-term and post-acute care. We further note that these initiatives often include the development of non-regulatory informational resources to support the specific implementation goal and align with the technical specifications already available in the Program for certification. To advance these efforts, we generally consider a range of factors including: stakeholder input and identification of clinical needs and clinical priorities, the evolution and adoption of health IT across the care continuum, the costs and benefits associated with any policy or implementation strategy related to care settings and sites of service, and potential regulatory burden and compliance timelines. Generally, ONC's approach can be summarized in three parts:

- First, ONC analyzes existing certification criteria to identify how such criteria may be applicable for medical specialties and sites of service.
- Second, ONC focuses on the real-time evaluation of existing and emerging standards to determine applicability to medical specialties and sites of service as well as to the broader care continuum, including the evaluation of such standards for inclusion in the ONC Interoperability Standards Advisory (ISA).[41]
- Third, ONC may work in collaboration with stakeholders to support the development of informational resources for medical specialties and sites of service for which ONC identifies a need to advance the effective implementation of certified health IT.

We believe this approach provides an economical, flexible, and responsive option for both health care providers and the health IT industry, which is also in alignment with the provisions of the Cures Act related to burden reduction and promoting interoperability. We are committed to continuing to work with stakeholders in this manner to encourage and advance the adoption of health IT to support medical specialties and sites of service, and to help ensure that providers have the tools they need to support patients at the point of care and that essential patient health information is available across a care settings.

[41] *https://www.healthit.gov/isa/.*

This section outlines our approach to implement Section 4001(b) of the Cures Act, which requires that the Secretary make recommendations for the voluntary certification of health IT for use by pediatric health providers and to adopt certification criteria to support the voluntary certification of health IT for use by pediatric health providers to support the health care of children. To be clear, and consistent with past practice, we do not recommend or propose a ''pediatric-specific track or program'' under the ONC Health IT Certification Program. This proposed rule outlines the certification criteria adopted in the 2015 Edition which we believe support the certification of health IT for pediatric care. Finally, it identifies the new and revised criteria proposed in this rule which we believe further support the voluntary certification of health IT for pediatric care. We have included in the appendix of this proposed rule a set of technical worksheets that can help inform your comments on the recommendations, the new and revised criteria in the Program that would also support pediatric care settings, and the overall approach we have herein described. These worksheets outline the following information:

- The alignment of each recommendation to the Children's Model EHR Format[42] as identified by stakeholders (see also Section VI.A.1 and 2 for further detail on the Children's Model EHR Format and the recommendations).
- The alignment of each recommendation to the 2015 Edition certification criteria and new or revised criteria described in this proposed rule (see also section VI.A.2.a and b).
- Potential supplemental items from the Children's Model EHR Format identified by ONC which relate to the primary recommendation and the related certification criteria.

We invite readers to use these worksheets to inform public comment on the recommendations and criteria described in Section VI.A.2 specifically as they relate to pediatric health care use cases. The comments received on these technical worksheets through this proposed rule will be used to inform the final recommendations for voluntary certification of health IT criteria for use in pediatric care. Furthermore, these comments, and the detailed insights received through stakeholder outreach, may inform the future development of a non-binding informational guide or resource to provide useful information for health IT developers and pediatric care providers seeking to successfully implement these health IT solutions in a clinical setting.

[42] *https://healthit.ahrq.gov/health-it-tools-and-resources/pediatric-resources/childrens-electronic-health-record-ehr-format.*

A. Health IT for Pediatric Setting

Section 4001(b)(iii) of the Cures Act—''Health information technology for pediatrics'' requires that:

- First, that the Secretary, in consultation with relevant stakeholders, shall make recommendations for the voluntary certification of health IT for use by pediatric health providers to support the health care of children, and
- Second, that the Secretary shall adopt certification criteria to support the voluntary certification of health IT for use by pediatric health providers to support the health care of children.

In this proposed rule, we describe our approach to stakeholder engagement, the analysis used to develop the recommendations, and the specific certification criteria we believe can support each recommendation.

1. Background and Stakeholder Convening

Over the past ten years, a number of initiatives have focused on the availability and use of effective health IT tools and resources for pediatric care. These have included a number of public-private partnerships including efforts between HHS, state agencies, and health systems for innovative projects that range from care coordination enterprise solutions to immunization information systems and to point of care solutions for specialty needs. In order to learn from and build upon these efforts, ONC has engaged with stakeholders in both the public and private sector including other federal, state and local government partners, health care providers engaged in the care of children, standards development organizations, charitable foundations engaged in children's health care research, and health IT developers supporting pediatric care settings.

For example, significant work has been done by the Agency for Healthcare Research and Quality (AHRQ), CMS, the Health Resources and Services Administration (HRSA), and organizations around the Children's Model EHR Format (Children's Format), which is critical to any discussion of the pediatric health IT landscape.[43] The Children's Format was authorized by the 2009 Children's Health Insurance Program Reauthorization Act (CHIPRA)[44] and developed by AHRQ in

[43] Agency for Health Care Information and Technology. Health Information Technology. *http://healthit.ahrq.gov/health-it-tools-and-resources/childrens-electronic-health-record-ehr-format* Accessed September, 2017.

[44] Public Law 111–3, section 401.

close collaboration with CMS. It was developed to bridge the gap between the functionality present in most EHRs currently available and the functionality that could optimally support the care of children. Specifically, the Children's Format provides information to EHR system developers and others about critical functionality and other requirements that are helpful to include in an EHR system to address health care needs specific to the care of children. The final version of the Children's Format,[45] released in 2015, consists of 47 high priority functional requirements in 19 topic areas that focus on improvements that would better support the safety and quality of care delivered to children. The Children's Format was intended as a starting point for developers, users, and purchasers for informing an approach for pediatric voluntary certification. We refer to the Voluntary Edition proposed rule for a description of ONC's prior discussion around the Children's Format (79 FR 10930).

In the summer of 2017, the American Academy of Pediatrics (AAP) reviewed the 2015 Format using a robust analytical process and engagement with their members. The result was a prioritized list of eight clinical priorities to support pediatric health care (''Priority List''). In October 2017, ONC held a technical discussion with stakeholders titled ''Health IT for Pediatrics'' with the specific purpose of obtaining input from an array of stakeholders in an effort to draw correlations between the pediatric providers' clinical priorities identified in the Priority List with the detailed technical requirements outlined in the Children's Format and the capabilities and standards that could be included in certified health IT. Through this collaborative approach, the meeting participants identified a set of priority needs for health IT to support pediatric care based upon those identified by the Priority List and the primary correlation to the Children's Format.

2. Recommendations for the Voluntary Certification of Health IT for Use in Pediatric Care

To support the first part of Section 4001(b) of the Cures Act, ONC considered the historical efforts on the Children's Model EHR Format, the input from stakeholders, and our own technical analysis and review of health IT capabilities and standards to develop a set of recommendations for voluntary certification for health IT for pediatric care. These include eight recommendations related to the Priority List:

- *Recommendation 1:* Use biometric-specific norms for growth curves and support growth charts for children.
- *Recommendation 2:* Compute weight-based drug dosage.
- *Recommendation 3:* Ability to document all guardians and caregivers.
- *Recommendation 4:* Segmented access to information.
- *Recommendation 5:* Synchronize immunization histories with registries.
- *Recommendation 6:* Age- and weight-specific single-dose range checking.
- *Recommendation 7:* Transferrable access authority.
- *Recommendation 8:* Associate maternal health information and demographics with newborn.

We also developed two additional recommendations beyond the Priority List which relate to other items within the Children's Format that are considered important to pediatric stakeholders. These additional recommendations, which we believe may be supported by certified health IT, are as follows:

- *Recommendation 9:* Track incomplete preventative care opportunities.
- *Recommendation 10:* Flag special health care needs.

In order to implement the second part of Section 4001(b) of the Cures Act for the adoption of certification criteria to support the voluntary certification of health IT for use by pediatric health care providers, we have identified both the 2015 Edition certification criteria and the new or revised criteria in this proposed rule that we believe support these 10 recommendations for health IT for pediatric care and sites of service. We direct readers to the appendix of this proposed rule for a set of technical worksheets which include a cross-walk of the various criteria specifically associated with each recommendation. These worksheets outline the following information:

- The alignment of each recommendation to the primary Children's Format[46] item identified by stakeholders.
- The alignment of each recommendation to the 2015 Edition certification criteria and new or revised criteria described in this proposed rule.
- Supplemental items from the Children's Format for each recommendation and the related certification criteria.

We invite readers to use these worksheets to inform public comment on the recommendations, the inclusion of specific items from the Children's Format, and the identified certification criteria as they relate specifically to use cases for pediatric care and sites of service. We also seek comment on the following:

1. Relevant gaps, barriers, safety concerns, and resources (including available best practices, activities, and tools) that may impact or support feasibility of the recommendation in practice.
2. Effective use of health IT itself in support of each recommendation as involves provider training, establishing workflow, and other related safety and usability considerations.
3. If any of the 10 recommendations should not be included in ONC's final recommendations for voluntary certification of health IT for pediatric care.
4. Any certification criteria from the Program that is identified for the 10 recommendations that should not be included to support the specific recommendation.

As stated in the worksheets located in the appendix, commenters are encouraged to reference the specific ''recommendation number'' (1–10) with the corresponding technical worksheet question number in their response. For example, ''Recommendation 1—Question 3''.

a. 2015 Edition Certification Criteria

In order to implement the second part of Section 4001(b) of the Cures Act to adopt certification criteria to support the voluntary certification of health IT for use by pediatric health providers to support the health care of children, we identified the following 2015 Edition certification criteria that support the recommendations. Within the technical worksheets in the appendix of this proposed rule, these criteria are noted under each recommendation to which they are correlated. The 2015 Edition criteria are as follows:

- ''API functionality'' criteria (§ 170.315(g)(7)–(g)(9)) which addresses many of the challenges currently faced by patients and by caregivers such as parents or guardians accessing child's health information, including the ''multiple portal'' problem, by potentially allowing individuals to aggregate health information from multiple sources in a web or mobile application of their choice.
- ''Care plan'' criterion (§ 170.315(b)(9)) which supports

[45] *https://healthit.ahrq.gov/sites/default/files/docs/citation/children-ehr-format-enhancement-final-recommendation-report-abridged.pdf.*

[46] *https://healthit.ahrq.gov/health-it-tools-and-resources/pediatric-resources/childrens-electronic-health-record-ehr-format.*

pediatric care by facilitating the documentation of electronic health information in a structured format to improve care coordination (80 FR 62648–62649).

• ''Clinical decision support'' (CDS) criterion (§ 170.315(a)(9)) which supports pediatric care by enabling interventions based on the capture of biometric data.

• ''Common Clinical Data Set'' (adopted in (§ 170.315(b)(4) and § 170.315(b)(5)) which includes *optional* pediatric vital sign data elements including as optional the reference range/growth curve for three pediatric vital signs—BMI percent per LOINC identifiers for age per sex, weight per length/sex, and head occipital-frontal circumference for children less than three years of age.

• ''Data segmentation for privacy'' send criterion and receive criterion (adopted in § 170.315(b)(7) and § 170.315(b)(8)) which provides the ability to: Create a summary record that is tagged at the document level as restricted and subject to re-disclosure; receive a summary record that is document-level tagged as restricted; separate the document-level tagged document from other documents received; and, view the restricted document without having to incorporate any of the data from the document.

• ''Demographics'' criterion (§ 170.315(a)(5)) which supports pediatric care through the capture of values and value sets relevant for the pediatric health care setting as well as allowing for improved patient matching which is a key challenge for pediatric care.

• ''Electronic Prescribing'' criterion (adopted in § 170.315(b)(3)) which includes an *optional* Structured and Codified Sig Format, which has the capability to exchange weight-based dosing calculations within the NCPDP SCRIPT 10.6 standard and limits the ability to prescribe all oral, liquid medications in only metric standard units of mL (*i.e.,* not cc) important for enabling safe prescribing practices for children.

• ''Family health history'' criterion (§ 170.315(a)(12)) which supports pediatric care because it leverages concepts or expressions for familial conditions, which are especially clinically relevant when caring for children.

• ''Patient health information capture'' criterion (§ 170.315(e)(3)) which supports providers' ability to accept health information from a patient or authorized representative. This criterion could support pediatric care through documentation of decision-making authority of a patient representative.

• ''Social, psychological, and behavioral data'' criterion § 170.315(a)(15) which supports integration of behavioral health data into a child's record across the care continuum by enabling a user to record, change, and access a patient's social, psychological, and behavioral data based using SNOMED CT® and LOINC® codes.

• ''Transitions of care'' criterion (§ 170.315(b)(1)) which supports structured transition of care summaries and referral summaries that help ensure the coordination and continuity of health care as children transfer between different clinicians at different health care organizations or different levels of care within the same health care organization;

• ''Transmission to immunization registries'' criterion (§ 170.315(f)(1)) which supports the safe and effective provision of child health care through immunizations and registry linkages. This criterion also provides the ability to request, access, and display the evaluated immunization history and forecast from an immunization registry for a patient. Immunization forecasting recommendations allow for providers to access the most complete and up-to-date information on a patient's immunization history to inform discussions about what vaccines a patient may need based on nationally recommended immunization recommendations (80 FR 62662–62664).

• ''View, download, and transmit to 3rd party'' (VDT) criterion (§ 170.315(e)(1)) which supports transferrable access authority for the pediatric health care setting and provides the ability for patients (and their authorized representatives) [47] to view, download, and transmit their health information to a 3rd party.

We note that some of these criteria may be updated based on proposals contained in this proposed rule; however, we believe that prior to any such updates, technology that is currently available and certified to these 2015 Edition criteria can make a significant impact in supporting providers engaged in the health care of children. We invite readers to use the technical worksheets in the appendix to this proposed rule to inform their public comment on the recommendations, the inclusion of specific items from the Children's Format, and the identified 2015 Edition certification criteria as they relate specifically to use cases for pediatric care and sites of service.

b. New or Revised Certification Criteria in This Proposed Rule

In order to implement the second part of Section 4001(b)(iii) of the Cures Act to adopt certification criteria to support the voluntary certification of health information technology for use by pediatric health providers to support the health care of children, we identified new or revised certification criteria in this proposed rule that support the recommendations. These new or revised criteria and standards in this proposed rule that would support pediatric settings include:

• New API criterion (§ 170.315(g)(10)) which would serve to implement the Cures Act requirement to permit health information to be accessed, exchanged, and used from APIs without special effort (see section IV.B.5 of this proposed rule).

• New ''DS4P'' criteria (two for C–CDA ((§ 170.315(b)(12)) and (§ 170.315(b)(13)) and one for FHIR (§ 170.315(g)(11))) that would support a more granular approach to privacy tagging data for health information exchange supported by either the C–CDA- or FHIR-based exchange standards (see section VI.A for a discussion of this criteria in relation to pediatric settings and section VI.B for discussion of these criteria in relation to Opioid Use Disorder).

• New electronic prescribing certification criterion (§ 170.315(b)(11)), which would supports improved patient safety and prescription accuracy, workflow efficiencies, and increased configurability of systems including functionality that could support pediatric medication management.

• USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference range/scale or growth curve for BMI percentile per age and sex, weight for age per length and sex, and head occipital-frontal circumference (and the criteria that include the USCDI).

Each of these proposed criteria are further described in other sections of this proposed rule; however, in this section of this proposed rule we specifically seek comment on the application of these criteria to pediatric use cases in support of our recommendations for the voluntary certification of health IT for pediatric care.

[47] The VDT criterion includes a ''patient-authorized representative'' concept that aligns with the use of the term under the EHR Incentive Program. A ''patient-authorized representative'' is defined as any individual to whom the patient has granted access to their health information (see also 77 FR 13720). However, consent is not needed for minors, for whom existing local, state, or federal law grants their parents or guardians access (see also 77 FR 13720).

For example, our proposal for three new 2015 Edition DS4P certification criteria (two for C–CDA ((§ 170.315(b)(12)) and (§ 170.315(b)(13)) and one for FHIR (§ 170.315(g)(11))) could provide functionality to address the concerns of multiple stakeholders in a range of specialty use cases—including pediatric care settings. In this section of this proposed rule, we seek comment specifically related to the inclusion of these criteria in our recommendations. Specifically, stakeholders have expressed the need to—based on the intended recipient of the data—to restrict granular pediatric health data at production. We believe these criteria could, for example, help enable providers to:

- Limit the sharing of reproductive and sexual health data from an EHR in order to protect the minor's privacy;
- Prevent disclosure of an emancipated minor's sensitive health information, while also permitting a parent or legal guardian to provide consent for treatment; and
- Segment child abuse information based on jurisdictional laws, which may have varying information sharing requirements for parents, guardians, and/or other possible legal representatives.

While health care providers should already have processes and workflows in place to address their existing compliance obligations, we recognize that more granular privacy markings at the point of data capture would further support existing and future priorities of pediatric health providers, as well as for multiple medical specialties and sites of service. We also recognize that such point of data capture markings can reduce administrative burden through efficiencies gained in streamlined compliance workflows.

We invite readers to use the technical worksheets in the appendix of this proposed rule to support public comment on the recommendations, the inclusion of specific items from the Children's Format, and the identified proposed new or revised certification criteria as they relate specifically to use cases for pediatric care and sites of service.

However, as discussed, through our experience and engagement with health care providers and health IT developers, we believe that in some cases information resources can aid in implementation in clinical settings. In the past, ONC has worked collaboratively with federal partners, health IT developers, and the health care community to support the development of non-regulatory informational resources that can provide additional support for health IT implementation (see, for example, the ONC Patient Engagement Playbook). Such a resource could include the recommendations and certification criteria here identified and synthesize these technical recommendations with information outside of the Program related to patient safety, usability, privacy and security, and other key considerations for successful implementation of a health IT system within a clinical setting. We believe that the creation of such a resource, in collaboration with clinical and technical stakeholders, would help support the advancement of health IT solutions for use in pediatric care and pediatric settings. We further include additional information on prior ONC initiatives related to health IT for pediatric settings as available on our website at *www.healthit.gov/pediatrics.*

B. Health IT and Opioid Use Disorder Prevention and Treatment—Request for Information

We have identified a need to explore ways to advance health IT across the care continuum to support efforts to fight the opioid epidemic. To that purpose, we seek comment in this proposed rule on a series of questions related to health IT functionalities and standards to support the effective prevention and treatment of opioid use disorder (OUD) across patient populations and care settings.

We recognize the significance of the opioid epidemic confronting our nation and the importance of helping to support health care providers committed to preventing inappropriate access to prescription opioids and providing safe, appropriate treatment.

HHS has a comprehensive strategy to combat the opioid crisis. It consists of five points that are focused on better: Addiction prevention, treatment, and recovery services; data; pain management; targeting of overdose reversing drugs; and research.[48] In support of this strategy, HHS will improve access to prevention, treatment, and recovery support services; target the availability and distribution of overdose-reversing drugs; strengthen public health data reporting and collection; support cutting-edge research; and advance the practice of pain management. To combat the opioid crisis, in October 2018, Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. It aims to expand treatment, recovery, and prevention initiatives for substance use disorder and also includes interoperability and health IT tools as a key part of the response to this crisis.

We believe health IT offers promising strategies to help medical specialties and sites of service as they combat opioid use disorder (OUD). For example, health IT has the potential to improve adherence to opioid prescribing guidelines and physician adherence to treatment protocols, to increase the safety of prescribing for controlled substances, to enhance clinician access to PDMPs, and to expand access to addiction treatment and recovery support services. Additionally, through the Program, our goal continues to be to improve access to data from disparate sources and help ensure that key data is consistently available to the right person, at the right place, and at the right time across the care continuum. One component of advancing that goal is through technical standards for exchanging health information that form an essential foundation for interoperability.

ONC has heard from stakeholders including policymakers, implementers, health care providers and patient advocacy groups that additional information is needed to assist in planning for the effective use of health IT in OUD prevention and treatment. We additionally recognize stakeholders' interest in the new opioid measures (Query of PDMP measure and Verify Opioid Treatment Agreement measure) included in CMS's Promoting Interoperability Programs (formerly known as the Medicare and Medicaid EHR Incentive Programs). These two measures support HHS initiatives related to the treatment of opioid and substance use disorders by helping health care providers avoid inappropriate prescriptions, improve coordination of prescribing amongst health care providers, and focus on the advanced use of certified health IT in care coordination for OUD prevention and treatment (83 FR 41644).

In order to support these efforts, in this proposed rule we outline a brief overview of some key areas of health IT implementation that could support OUD prevention and treatment. These include consideration of current health IT certification criteria included in the 2015 Edition, revised or new certification criteria as outlined in this proposed rule, and current health IT initiatives underway in the health care industry or health IT industry which intersect with ONC policy goals. In this section of the proposed rule, we request public comment specifically from the perspective of how our existing Program

[48] *https://www.hhs.gov/opioids/.*

requirements and proposals in this rulemaking may support use cases related to OUD prevention and treatment and if there are additional areas that ONC should consider for effective implementation of health IT-enabled OUD prevention and treatment. We seek comment from this perspective on the identification of 2015 Edition certification criteria, the proposals for revised or new certification criteria, and the potential future consideration of emerging technologies described in various initiatives.

1. 2015 Edition Certification Criteria

We seek public comment on how the existing 2015 Edition certification criteria as well as proposals within this proposed rule for revised or new criteria support OUD prevention and treatment. Specifically, we seek comment on certification criteria previously adopted in the 2015 Edition that can support clinical priorities, advance interoperability for OUD (including care coordination and the effective use of health IT for the treatment and prevention of OUD). In this proposed rule, we summarize some of these 2015 Edition certification criteria identified and indicate how they support care coordination, the prevention of OUD and overdose, and the detection of opioid misuse, abuse, and diversion.

We have also below identified the proposals for revised or new 2015 Edition criteria within this proposed rule that we believe can support clinical priorities, advance interoperability for OUD (including care coordination and also the effective use of health IT for the treatment and prevention of OUD). We welcome input from stakeholders specifically on these criteria within the context of OUD prevention and treatment, as well as input on the identification of other criteria included either in the 2015 Edition and/or that are proposed in other parts of this rule that may be considered a clinical and interoperability priority for supporting OUD treatment and prevention.

We have identified several 2015 Edition certification criteria available now for certification in the Program which could support care coordination and the prevention and detection of opioid misuse, abuse, and diversion. They are:

- The ''transitions of care'' criterion (§ 170.315(b)(1)) supports structured transition of care summaries and referral summaries that help ensure the coordination and continuity of health care as patients transfer between different clinicians at different health care organizations or different levels of care within the same health care organization. This criteria supports the ability to transmit a summary care record to support an individual with OUD upon discharge from an inpatient setting or from a primary care provider to another setting for their care.
- The ''clinical information reconciliation and incorporation'' criterion (§ 170.315(b)(2)) allows clinicians to reconcile and incorporate patient health information sent from external sources to maintain a more accurate and up-to-date patient record. This process could help—for example—reduce opioid related errors regarding patients who use multiple pharmacies, have co-morbidity factors, and visit multiple clinicians.
- The ''electronic prescribing'' criterion (§ 170.315(b)(3)) provides a way to write and transmit prescription information electronically. This criterion facilitates appropriate opioid prescribing by simplifying the review of prescription information during follow-up visits or transitions to other clinicians, by allowing prescribers to communicate prescription-related messages to pharmacies electronically and by capturing and transmitting medication histories that are shared with PDMPs. In this proposed rule, we propose to update the existing electronic prescribing certification criterion as described in section IV.B.2 of this proposed rule.
- The ''patient health information capture'' (§ 170.315(e)(3)) allows clinicians to incorporate unstructured patient generated health data or data from a non-clinical setting into a patient record. The CMS Promoting Interoperability Programs for eligible hospitals includes a new optional measure which is focused on verifying the existence of a signed Opioid Treatment Agreement for certain patients when a controlled substance is prescribed and incorporating it into the record. In the Hospital Inpatient Prospective Payment Systems final rule, CMS recognized this certification criterion's potential to support this goal within a certified health IT system (83 FR 41654).
- The ''social, psychological, and behavioral data'' criterion (§ 170.315(a)(15)) can help to provide a more complete view of a patient's overall health status. This is important to help provide a ''whole-patient'' approach to the treatment of substance use disorders included as part of Medicated-Assisted Treatment (MAT) that involves the use of FDA-approved medications, in combination with counseling and behavioral therapies, to treat individuals recovering from OUD. This data can help to improve care coordination and lead to the identification of appropriate social supports and community resources.

We seek comment on how these criteria and what additional 2015 Edition certification criteria may be considered a clinical and interoperability priority for supporting OUD treatment and prevention. We also seek comment on the value of developing a potential future non-binding informational guide or resource to provide useful information for OUD providers and sites of service related to specific clinical priorities and use cases of focus.

2. Revised or New 2015 Edition Certification Criteria in This Proposed Rule

This proposed rule contains additional proposals to revise or add new criteria to the Program to better support care across the continuum. We believe these criteria and standards, highlighted below, can also support treatment and prevention of OUD. We seek comment specifically on the applicability of these criteria to the OUD use case. They are:

- *USCDI:* As detailed in section IV.B.1, we are proposing to adopt the USCDI as a standard (§ 170.213) which would establish a minimum set of data classes (including structured data fields) that are required to be interoperable nationwide, and is designed to be expanded in an iterative and predictable way over time. The USCDI Version 1 (USCDI v1) builds upon the 2015 Edition CCDS and includes a common set of data classes that can be supported by commonly used standards. It includes the 2015 Edition CCDS data elements, such as medications. It also includes two new data classes, titled ''clinical notes'' and ''provenance,'' which would help facilitate interoperable exchange and the trustworthiness of the data being exchanged. These enhancements to the comprehensiveness and reliability of the data being exchanged could help empower physicians in the prevention and detection of opioid misuse, abuse, and diversion.

In addition, because we propose to adopt the USCDI as a standard, health IT developers would be allowed to take advantage of the Maintenance of Certification requirements described in section VII.B.5 of this proposed rule. Therefore, the USCDI would have the potential to further benefit clinical priorities and interoperability for OUD, including safe and appropriate opioid prescribing, through the ability to voluntarily implement and use a new version of an adopted standard or

implementation specification so long as certain conditions are met, including the new version being approved by the National Coordinator for use in certification through the Standards Version Advancement Process. We seek comment on how this proposal would further support the access, exchange, and use of additional and future data classes (including structured data fields) in more care and practice settings specifically as related to the prevention and treatment of OUD.

• *Standardized API:* We are proposing new API functionality through the adoption of a new API certification criterion (§ 170.315(g)(10)), which serves to implement the Cures Act requirement to permit health information to be accessed, exchanged, and used from APIs without special effort. This criterion would enable efficient exchange of health information using modern internet technologies and thus enable collaborative, patient-driven, integrated care for individuals recovering from OUD.

• *Data Segmentation for Privacy and Consent Management:* As discussed in section IV.B.7, we are also proposing to remove the current 2015 Edition DS4P—send (§ 170.315(b)(7)) and DS4P—receive (§ 170.315(b)(8)) certification criteria. We propose to replace these two criteria with three new 2015 Edition DS4P certification criteria (two for C–CDA ((§ 170.315(b)(12)) and (§ 170.315(b)(13)) and one for FHIR (§ 170.315(g)(11))) that would support a more granular approach to privacy tagging data for health information exchange supported by either the C–CDA- or FHIR-based exchange standards. We believe this proposal would offer functionality that is more valuable to providers and patients, especially given the complexities of the privacy law landscape for multiple care and specialty settings. We also believe this proposal could lead to more complete records, contribute to patient safety, and enhance care coordination. Additionally, we believe this proposal may support a more usable display of OUD information at the request of patients within an EHR and we invite input on best practices, including the processes and methods by which OUD information should be displayed.

• *Electronic Prescribing and PDMPs:* As discussed in section IV.B.2, we are proposing to remove the current 2015 Edition electronic prescribing certification criterion (§ 170.315(b)(3)) and replace this criterion with a new electronic prescribing certification criterion (§ 170.315(b)(11)) that would support improved patient safety and prescription accuracy, create workflow efficiencies, reduce testing requirements, and increase configurability of systems. This new proposed criterion includes the addition of Risk Evaluation and Mitigation Strategy (REMS) messages. We believe this proposal would help address challenges discussed in the CMS Hospital Inpatient Prospective Payment Systems final rule (83 FR 41651) and Medicare Physician Fee Schedule proposed rule (83 FR 35704) by strengthening clinical and administrative efficiency, helping move the industry forward by adopting more current standards for electronic prescribing, and harmonizing efforts across federal agencies in the prevention and treatment of OUD. In addition, the FDA has enacted an opioids medications REMS program for opioid analgesics [49] mandating prescriber and patient education to encourage proper patient screening and appropriate monitoring. Adoption of the new proposed criterion also supports the efficient and accurate exchange of medication history transactions between providers and pharmacies, and between pharmacies and state PDMPs.

3. Emerging Standards and Innovations

In addition to the certification criteria established in the 2015 Edition final rule and proposed in this rule, ONC is engaged in a number of health IT and standards initiatives exploring innovation and emerging standards to inform future health IT policy. In some cases, these efforts may not be mature enough or best suited for adoption in the Program; however, we seek comment on the potential consideration of these initiatives for future direction of ONC policy.

• *CDS Hooks:* Improving how opioids are prescribed through evidence-based guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the risk of opioid misuse, abuse, or overdose from these drugs. In response to the critical need for consistent and current opioid prescribing guidelines, the Centers for Disease Control and Prevention (CDC) released the Guideline for Prescribing Opioids for Chronic Pain.[50] While progress has been made in training prescribers and fostering the adoption of the CDC guideline, the President's Opioid Commission [51] acknowledged that ''not all states have adopted the guideline, not all physicians are aware of them, and sound opioid prescribing guidelines are far from universally followed.'' Clinical decision support (CDS) Hooks is a health IT specification that has the potential to positively affect prescriber adoption of evidence-based prescribing guidelines by invoking patient-specific clinical support from within the clinician's EHR workflow. ONC is currently collaborating with CDC on a project to translate the CDC guideline into standardized, shareable, computable decision support artifacts using CDS Hooks. We recognize that CDS Hooks is still an emerging technology and seek input on the adoption of the CDS Hooks specification for opioid prescribing and OUD prevention and treatment. We also request public comment on other health IT solutions and effective approaches to improve opioid prescription practices and clinical decision support for OUD.

• *Care Plan FHIR Resource:* A shared care plan is a critical concept for managing an individual's health across a continuum that includes both clinical and non-clinical settings [52] and can help enable more informed and useful connections among all the stakeholders engaged in preventing or treating OUD. For those in recovery from OUD, the care plan can enable patients to access their care plan information and coordinate their care with approved community care providers which is critical and part of evidence-based recovery treatment services. In 2015, the ONC HITPC recommended that the National Coordinator accelerate the implementation of dynamic, shared, longitudinal care plans that incorporate information from both clinical and non-clinical services and empower individuals to manage their own health and care.[53] A consideration for HHS as part of this earlier recommendation included looking at the future standards development needed to transition from the static care plan documentation (document template in C–CDA R2.1) to a dynamic shared care plan that supports more robust care coordination.[54] We believe HL7 standards and standardized APIs can elevate care coordination and care management across the continuum,

[49] *https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm.*

[50] *Guideline for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.*

[51] President's Opioid Commission: *https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.*

[52] *https://www.healthit.gov/hitac/events/policy-advanced-health-models-and-meaningful-use-workgroup-8.*

[53] *https://www.healthit.gov/sites/default/files/facas/HITPC_AHM_Hearing_Transmittal_08-11-2015_0.pdf.*

[54] *https://www.healthit.gov/hitac/events/policy-advanced-health-models-and-meaningful-use-workgroup-8.*

including for those providers without EHRs, whether for opioid use disorder related treatment, primary health, or other problems. Indeed, numerous efforts are underway within HL7 and other collaborations to standardize ''care plans'' and their content using FHIR and the C–CDA. From a technical perspective and in the context of the proposals focused on the USCDI standard, the ARCH standard, the new proposed API certification criterion at 170.315(g)(10), and the voluntary Standards Version Advancement Process Maintenance of Certification requirement described in section VII.B.5 of this proposed rule, we can see a future where a (g)(10)–certified API would be capable of supporting care plan data. We request public comment on the current maturity of existing and forthcoming technical specifications to support care plan/care plan data as well as specific information that could be prioritized within a future USCDI data class focused on care plans.

In addition to commenting on the criteria noted in this section, we also encourage stakeholders to participate in the ISA process.[55] The ISA represents the model by which ONC coordinates the identification, assessment, and public awareness of interoperability standards and implementation specifications. ONC encourages all stakeholders to implement and use the standards and implementation specifications identified in the ISA as applicable to the specific interoperability needs they seek to address and encourages pilot testing and other industry experience adopting standards and implementation specifications identified as ''emerging'' in the ISA. The web-based version of the ISA documents known limitations, preconditions, and dependencies, and provide suggestions for security best practices in the form of security patterns for referenced standards and implementation specifications when they are used to address a specific clinical health IT interoperability need.

Additionally, through the ISA process, stakeholders are encouraged to comment on the outlined standards and implementation specifications, as ONC updates the ISA regularly. ONC has developed and has plans to develop further ISA content to highlight standards and implementation specifications that support the prevention and treatment of OUD/substance use disorder (SUD). For example, the NCPDP SCRIPT standard allows a prescriber to request a patient's medication history from a state PDMP via the RxHistoryRequest and RxHistoryResponse. ONC is also working to enhance the ISA to make it easier for stakeholders to find standards and implementation specifications related to high-priority use cases, such as OUD/SUD. The ISA has a comment process that occurs each year[56] and we encourage stakeholders to participate in that process to comment on other standards and implementation specifications that currently exist in the ISA or that the industry and its stakeholders feel should be added to the ISA that support OUD/SUD prevention, treatment, monitoring, and care coordination.

4. Additional Comment Areas

We further seek comment on effective approaches for the successful dissemination and adoption of standards including the NCPDP SCRIPT 2017071 standard (see section IV.B.2) that can support the exchange of PDMP data for integration into EHRs and also enable further adoption and use of Electronic Prescribing of Controlled Substances (EPCS). Regarding integration of health IT with PDMPs and EPCS, we believe there are real and perceived challenges and opportunities that involve policy and technical components. As we explore these issues in collaboration with industry and stakeholders, we seek comment on the priority challenges and opportunities for these topics and on any technical and policy distinctions, as appropriate.

We also note that there are many federal initiatives separate from ONC proposed rulemaking and the Program that exist within HHS programs including, but not limited to, CMS Medicaid and Medicare programs. For example, Medicare now provides separate payment for psychiatric collaborative care model/behavioral health integration and chronic care management services (see 81 FR 80233, and 80247), and Medicaid issued guidance on leveraging technology to address the opioid crisis at enhanced funding matches[56] and also includes SUD health IT in standard terms and conditions as part of 1115 waiver requirements.

In addition, CMS sought comment for consideration through separate rulemaking in both the 2019 Physician Fee Schedule proposed rule (83 FR 35923) and Hospital Inpatient Prospective Payment Systems proposed rule (83 FR 20528) regarding whether they should adopt the NCPDP SCRIPT 2017071 standard to facilitate future reporting of the proposed Query of PDMP quality measure. As noted in the Hospital Inpatient Prospective Payment Systems final rule, a few commenters supported the use of NCPDP Script Standard Implementation Guide Version 2017071 medication history transactions for PDMP queries and response. Additionally, CMS encourages advances in standards and their use to deliver innovative, interoperable solutions that will seamlessly integrate PDMP query functionality into clinician-friendly, patient- centered CEHRT-enabled workflows that facilitate safer, more informed prescribing practices and improved patient outcomes (83 FR 41651).

We seek comment on how successful implementation of health IT that supports OUD can aid in the achievement of national and programmatic goals, especially where they may align with initiatives across HHS and with stakeholder and industry led efforts.

Finally, we seek comment on a topic that involves health IT for both pediatric care and OUD prevention and treatment—Neonatal Abstinence Syndrome (or NAS). In its September 2018 report, *Facing Addiction in America: The Surgeon General's Spotlight on Opioids,* the HHS Office of the Surgeon General describes how the incidence of Neonatal Abstinence Syndrome (or NAS), has increased dramatically in the last decade along with increased opioid misuse. Newborns may experience NAS, a withdrawal syndrome, following exposure to drugs while in the mother's womb. NAS is an expected and treatable condition following repeated maternal substance use and abuse during pregnancy, which may have long-term health consequences for the infant.

Immediate newborn NAS signs include neurological excitability, gastrointestinal dysfunction, and autonomic dysfunction. Newborns with NAS are more likely than other babies to have low birthweight and respiratory complications. ONC believes the pediatric clinical health IT recommendations proposed in this rule (including Priority 8, which includes the linkage of health data in records of the mother and newborn) are important for supporting newborns at birth and as they grow and receive care in various settings. As such, we invite comment on:

- The effective use of health IT itself in support of the NAS use case as involves provider training, establishing

[55] To learn more about, and/or participate in, the ISA process, please visit *https://www.healthit.gov/isa/.*

[56] *https://www.medicaid.gov/federal-policy-guidance/downloads/smd18006.pdf.*

workflow, and other related safety and usability considerations.

• Existing and potential tools, such as decision support or clinical quality measurement, for supporting children with NAS and on the specific data elements related to the care of these children and use of these tools in practice.

• Identification of any related criteria and the respective corresponding proposed pediatric recommendation for the voluntary certification of health IT for use in pediatric care that supports the NAS use case including but not limited to recommendation number 8 noted above.

We welcome public comment on these health IT policies, functionalities and standards to support providers engaged in the treatment and prevention of OUD.

VII. Conditions and Maintenance of Certification

Section 4002 of the Cures Act requires the Secretary of HHS, through notice and comment rulemaking, to establish Conditions and Maintenance of Certification requirements for the Program. Specifically, health IT developers or entities must adhere to certain Conditions and Maintenance of Certification requirements concerning information blocking; appropriate exchange, access, and use of electronic health information; communications regarding health IT; application programming interfaces (APIs); real world testing for interoperability; attestations regarding certain Conditions and Maintenance of Certification requirements; and submission of reporting criteria under the EHR reporting program.

A. Implementation

To implement Section 4002 of the Cures Act, we propose an approach whereby the Conditions and Maintenance of Certification express both initial requirements for health IT developers and their certified Health IT Module(s) as well as ongoing requirements that must be met by both health IT developers and their certified Health IT Module(s) under the Program. If these requirements are not met, then the health IT developer may no longer be able to participate in the Program and/or its certified health IT may have its certification terminated. We propose to implement each Cures Act Condition of Certification with further specificity as it applies to the Program. We also propose to establish the Maintenance of Certification requirements for each Condition of Certification as standalone requirements. This approach would establish clear baseline technical and behavior Conditions of Certification requirements with evidence that the Conditions of Certification are continually being met through the Maintenance of Certification requirements.

B. Provisions

1. Information Blocking

The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, not take any action that constitutes ''information blocking'' as defined in section 3022(a) of the PHSA (see 3001(c)(5)(D)(i) of the PHSA). We propose to establish this information blocking Condition of Certification in § 170.401. The Condition of Certification prohibits any health IT developer under the Program from taking any action that constitutes information blocking as defined by section 3022(a) of the PHSA and proposed in § 171.103.

We clarify that this proposed ''information blocking'' Condition of Certification and its requirements would be substantive requirements of the Program and would use the definition of ''information blocking'' established by section 3022(a) of the PHSA and as also proposed in § 171.103, as it relates to health IT developers of certified health IT. In addition to ONC's statutory authority for this Condition of Certification, the HHS Office of the Inspector General (OIG) has both investigatory and enforcement authority over information blocking and may issue civil money penalties for information blocking conducted by health IT developers of certified health IT, health information networks and health information exchanges. OIG may also investigate health care providers for information blocking for which health care providers could be subject to disincentives.

We refer readers to section VII.D of this proposed rule for additional discussion of ONC's enforcement of this and other proposed Conditions and Maintenance of Certification requirements. We also refer readers to section VIII of this proposed rule for our proposals to implement the information blocking provisions of the Cures Act, including proposed § 171.103.

We do not, at this time, propose any associated Maintenance of Certification requirements for this Condition of Certification.

2. Assurances

The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, provide assurances to the Secretary, unless for legitimate purposes specified by the Secretary, that it will not take any action that constitutes information blocking as defined in section 3022(a) of the PHSA, or any other action that may inhibit the appropriate exchange, access, and use of electronic health information (EHI). We propose to implement this Condition of Certification and accompanying Maintenance of Certification requirements in § 170.402. As a Condition of Certification requirement, a health IT developer must comply with the Condition as recited here and in the Cures Act. We refer readers to section VIII of this proposed rule for the proposed reasonable and necessary activities specified by the Secretary, which constitute the exceptions to the information blocking definition.

We also propose to establish more specific Conditions and Maintenance of Certification requirements for a health IT developer to provide assurances that it does not take any action that may inhibit the appropriate exchange, access, and use of EHI. These proposed requirements serve to provide further clarity under the Program as to how health IT developers can provide such broad assurances with more specific actions.

a. Full Compliance and Unrestricted Implementation of Certification Criteria Capabilities

We propose, as a Condition of Certification, that a health IT developer must ensure that its health IT certified under the ONC Health IT Certification Program (Program) conforms to the full scope of the certification criteria to which its health IT is certified. This has always been an expectation of ONC and users of certified health IT and, importantly, a requirement of the Program. We believe, however, that by incorporating this expectation and requirement as a Condition of Certification under the Program, there would be assurances, and documentation via the ''Attestations'' Condition and Maintenance of Certification requirements proposed in § 170.406, that all health IT developers fully understand their responsibilities under the Program, including not to take any action with their certified health IT that may inhibit the appropriate exchange, access, and use of EHI. To this point, certification criteria are designed and issued so that certified health IT can support interoperability and the appropriate exchange, access, and use of electronic health information.

We propose that, as a complementary Condition of Certification, health IT developers of certified health IT must provide an assurance that they have made certified capabilities available in ways that enable them to be implemented and used in production environments for their intended purposes. More specifically, developers would be prohibited from taking any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the scope of the technology's certification. Such actions may inhibit the appropriate access, exchange, or use of EHI and are therefore contrary to this proposed Condition of Certification and the statutory provision that it implements. While such actions are already prohibited under the Program (80 FR 62711), making these existing requirements explicit would ensure that health IT developers are required to attest to them on a regular basis pursuant to the Condition of Certification proposed in § 170.406, which will in turn provide additional assurances to the Secretary that developers of certified health IT support and do not inhibit appropriate access, exchange, or use of EHI.

By way of example, actions that would violate this aspect of the proposed Condition include failing to fully deploy or enable certified capabilities; imposing limitations (including restrictions) on the use of certified capabilities once deployed; or requiring subsequent developer assistance to enable the use of certified capabilities, contrary to the intended uses and outcomes of those capabilities (*see* 80 FR 62711). The Condition would also be violated were a developer to refuse to provide documentation, support, or other assistance reasonably necessary to enable the use of certified capabilities for their intended purposes (*see* 80 FR 62711). More generally, any action that would be likely to substantially impair the ability of one or more users (or prospective users) to implement or use certified capabilities for any purpose within the scope of applicable certification criteria would be prohibited by this Condition (*see* 80 FR 62711). Such actions may include imposing limitations or additional types of costs, especially if these were not disclosed when a customer purchased or licensed the certified health IT (*see* 80 FR 62711).

b. Certification to the ''Electronic Health Information Export'' Criterion

We propose, as a Condition of Certification requirement, that a health IT developer that produces and electronically manages EHI must certify health IT to the 2015 Edition ''electronic health information export'' certification criterion in § 170.315(b)(10). We discuss the proposed ''electronic health information (EHI) export'' criterion in section IV.B.4 of this proposed rule. Further, as a Maintenance of Certification requirement, we propose that a health IT developer that produces and electronically manages EHI must provide all of its customers of certified health IT with health IT certified to the functionality included in § 170.315(b)(10) within 24 months of a subsequent final rule's effective date or within 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition, whichever is longer. Consistent with these proposals, we also propose to amend § 170.550 to require that ONC–ACBs certify health IT to the proposed 2015 Edition ''EHI export'' when the health IT developer of the health IT presented for certification produces and electronically manages EHI.

As discussed in section IV.C.1 of this proposed rule, the availability of the capabilities in the proposed 2015 Edition ''EHI export'' certification criterion to providers and patients would promote access, exchange, and use of EHI to facilitate health care providers in switching practices and health IT systems and patients' electronic access to all their health information stored by a provider. As such, health IT developers with health IT certified to the proposed 2015 Edition ''EHI export'' certification criterion that is made available to its customers provides assurances that the developer is not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI.

c. Records and Information Retention

We propose that, as a Maintenance of Certification requirement, a health IT developer must, for a period of 10 years beginning from the date of certification, retain all records and information necessary that demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program. In other words, records and information should be retained starting from the date a developer first certifies health IT under the Program and applies separately to each unique Health IT Module (or Complete EHR, as applicable) certified under the Program. This retention of records is necessary to verify health IT developer compliance with Program requirements, including certification criteria and Conditions of Certification. We believe that 10 years is an appropriate period of time given that many users of certified health IT participate in various CMS programs, as well as other programs, that require similar periods of records retention. We also refer readers to section VII.D.3.c of this preamble for additional discussion of records access to information necessary to enforce the Conditions and Maintenance of Certification.

In an effort to reduce administrative burden, we also propose, that in situations where applicable certification criteria are removed from the Code of Federal Regulations before the 10 years have expired, records must only be kept for 3 years from the date of removal for those certification criteria and related Program provisions unless that timeframe would exceed the overall 10-year retention period. This ''3-year from the date of removal'' records retention period also aligns with the records retention requirements for ONC–ACBs and ONC–ATLs under the Program.

We encourage comment on these proposals and whether the proposed requirements can provide adequate assurances that certified health IT developers are demonstrating initial and ongoing compliance with the requirements of the Program; and thereby ensuring that certified health IT can support interoperability, and appropriate exchange, access, and use of EHI.

d. Trusted Exchange Framework and the Common Agreement—Request for Information

The Cures Act added section 3001(c)(9) to the PHSA, which requires the National Coordinator to work with stakeholders with the goal of developing or supporting a Trusted Exchange Framework and a Common Agreement (collectively, ''TEFCA'') for the purpose of ensuring full network-to-network exchange of health information. Section 3001(c)(9)(B) outlines a process for establishing a TEFCA between health information networks (HINs)—including provisions for the National Coordinator, in collaboration with the NIST, to provide technical assistance on implementation and pilot testing of the TEFCA. In accordance with section 3001(c)(9)(C), the National Coordinator shall publish the TEFCA on its website and in the **Federal Register**, as well as annually publish on its website a directory of the HINs that have adopted the Common Agreement and are capable of trusted exchange pursuant to the Common Agreement. The process, application, and construction of the

TEFCA are further outlined in section 3001(c)(9)(D), including requiring that the Secretary shall through notice and comment rulemaking, establish a process for HINs that voluntarily adopt the TEFCA to attest to such adoption. We request comment as to whether certain health IT developers should be required to participate in the TEFCA as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI. We would expect that such a requirement, if proposed in a subsequent rulemaking, would apply to health IT developers that have a Health IT Module(s) certified to any of the certification criteria in §§ 170.315(b)(1), (c)(1) and (c)(2), (e)(1), (f), and (g)(9) through (11); and provide services for connection to health information networks (HINs). These services could be routing EHI through a HIN or responding to requests for EHI from a HIN.

We have identified health IT developers that certify health IT to the criteria above because the capabilities included in the criteria support access and exchange of EHI. Therefore, we believe such health IT developers, as opposed to a health IT developer that only supports clinical decision support (§ 170.315(a)(9)) with its certified health IT, would be best suited to participate in the Trusted Exchange Framework and adhere to the Common Agreement. Similarly, we believe that many such health IT developers with the identified certified health IT would be in position, and requested by customers, to provide connection services to HINs. When such criteria are met (certified to the identified criteria above and actually providing connection services), participation in the Trusted Exchange Framework and adherence to the Common Agreement are consistent with this Condition and Maintenance of Certification as specified by the Cures Act, the intent of Congress to establish widespread interoperability and exchange of health information without information blocking, and supports ONC's responsibility, as established by the HITECH Act, to develop and support a nationwide health IT infrastructure that allows for the electronic use and exchange of information. More specifically, by participating in the Trusted Exchange Framework and adhering to the Common Agreement, these health IT developers provide assurances that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI. For more information on the Trusted Exchange Framework and Common Agreement, please visit: *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.*

In consideration of this request for comment, we welcome comment on the certification criteria we have identified as the basis for health IT developer participation in the Trusted Exchange Framework and adherence to the Common Agreement, other certification criteria that would serve as a basis for health IT developer participation in the Trusted Exchange Framework and adherence to the Common Agreement, and whether the current structure of the Trusted Exchange Framework and Common Agreement are conducive to health IT developer participation and in what manner.

3. Communications

The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, does not prohibit or restrict communication regarding the following subjects:

- The usability of the health information technology;
- The interoperability of the health information technology;
- The security of the health information technology;
- Relevant information regarding users' experiences when using the health information technology;
- The business practices of developers of health information technology related to exchanging electronic health information; and
- The manner in which a user of the health information technology has used such technology.

We propose to implement this Condition of Certification and its requirements in § 170.403. The Cures Act placed no limitations on the protection of the communications delineated above (referred to hereafter as ''protected communications''). As such, we propose to broadly interpret the subject matter of communications that are protected from developer prohibition or restriction as well as the conduct of developers that implicate the protection afforded to communications by this Condition of Certification and discuss this proposed approach in detail below. While we propose to implement a broad general prohibition against developers imposing prohibitions and restrictions on protected communications, we also recognize that there are circumstances where it is both legitimate and reasonable for developers to limit the sharing of information about their products. As such, we propose to allow developers to impose prohibitions or restrictions on protected communications in certain narrowly defined circumstances. In order for a prohibition or restriction on a protected communication to be permitted, we propose that it must pass a two-part test. First, the communication that is being prohibited or restricted must not fall within a class of communication about which no restriction or prohibition would ever be legitimate or reasonable—such as communications required by law, made to a government agency, or made to a defined category of safety organizations—and which we refer to hereafter as ''communications with unqualified protection.'' Second, to be permitted, a developer's prohibition or restriction must also fall within a prescribed category of circumstances for which we propose it is both legitimate and reasonable for a developer to limit the sharing of information about its products. This would be because of the nature of the relationship between the developer and the communicator or because of the nature of the information that is, or could be, the subject of the communication (referred to hereafter as ''permitted prohibitions and restrictions''). A restriction or prohibition that does not satisfy this two-part test will contravene this Condition of Certification. As discussed in more detail below, we propose that this two-part test strikes a reasonable balance between the need to promote open communication about health IT and related business practices, and the need to protect the legitimate interests of health IT developers and other entities.

a. Background and Purpose

This Condition of Certification addresses industry practices that severely limit the ability and willingness of health IT customers, users, researchers, and other stakeholders who use and work with health IT to openly discuss and share their experiences and other relevant information about the performance of health IT, including the ability of health IT to exchange health information electronically. These practices result in a lack of transparency around health IT that can contribute to and exacerbate patient safety risks, system security vulnerabilities, and product performance issues. As discussed below, these issues have been documented and reported on over a number of years.

The challenges presented by health IT developer actions that prohibit or

restrict communications have been examined for some time. The problem was identified in a 2012 report by the Institute of Medicine of the National Academies (IOM) entitled ''Health IT and Patient Safety: Building Safer Systems for Better Care'' [57] (IOM Report). The IOM Report stated that health care providers, researchers, consumer groups other health IT users lack information regarding the functionality of health IT.[58] The IOM Report observed, relatedly, that many developers restrict the information that users can communicate about developers' products through nondisclosure clauses, confidentiality clauses, intellectual property protections, hold-harmless clauses, and other boilerplate contract language.[59] Importantly, the IOM Report found that such clauses discourage users from sharing information about patient safety risks related to health IT, which significantly limits the ability of health IT users to understand how health IT impacts patient safety.[60] The report stressed the need for health IT developers to enable the free exchange of information regarding the experience of using their health IT products, including the sharing of screenshots.[61]

Other close observers of health IT have similarly noted that broad restrictions on communications can inhibit the communication of information about errors and adverse events.[62] Concerns have also been raised by researchers of health IT products,[63] who emphasize that confidentiality and intellectual property provisions in contracts often place broad and unclear limits on authorized uses of information related to health IT, which in turn seriously impacts the ability of researchers to conduct and publish their research.[64]

The issue of health IT developers prohibiting or restricting communications about health IT has been the subject of a series of hearings by the Senate Committee on Health, Education, Labor and Pensions (HELP Committee), starting in the spring of 2015. During several hearings, stakeholders emphasized the lack of transparency around the performance of health IT in a live environment, noting that this can undermine a competitive marketplace, hinder innovation, and prevent improvements in the safety and usability of the technology.[65] [66] Additionally, the HELP Committee indicated serious concerns regarding the reported efforts of health IT developers to restrict, by contract and other means, communications regarding user experience, including information relevant to safety and interoperability.[67] When one Senator asked a panel of experts—which included a health IT developer—if there were any reasons for health IT contracts to have confidentiality clauses restricting users of health information technology from discussing their experience of using the health IT, all panel members agreed that such clauses should be prohibited.[68]

Prior to the HELP Committee hearings described above, the issue of developers prohibiting and restricting communications about the performance of their health IT was also addressed in House Energy and Commerce Committee hearings when committee members heard testimony and held discussions related to the Cures Act.[69] Commentary by witnesses at the hearings emphasized the need to ensure that health IT products are safe and encouraged the availability of information around health IT products to improve quality and ensure patient safety.

Developer actions that prohibit or restrict communications about health IT have also been the subject of investigative reporting.[70] A September 2015 report examined eleven contracts between health systems and major health IT developers and found that, with one exception, all of the contracts protected large amounts of information from being disclosed, including information related to safety and performance issues.[71] The report stated that broad confidentiality and intellectual property protection clauses were the greatest barriers to allowing the communication of information regarding potential safety issues and adverse events.[72]

Finally, ONC has itself been made aware of health IT developer contract language that purports to prohibit the disclosure of information about health IT, including even a customer's or user's opinions and conclusions about the performance and other aspects of the technology. Our extensive interactions with health care providers, researchers, and other stakeholders consistently indicate that such terms are not uncommon and that some developers may actively enforce them and engage in other practices to discourage communications regarding developers' health IT products and related business practices.

This proposed Condition of Certification is needed to significantly improve transparency around the functioning of health IT in the field. This will help ensure that the health IT ultimately selected and used by health care providers and others functions as expected, is less likely to have safety issues or implementation difficulties, enables greater interoperability of health information, and more fully allows users to reap the benefits of health IT utilization, including improvements in care and quality, and reductions in costs.

b. Condition of Certification Requirements

i. Protected Communications and Communicators

We propose that the protection afforded to communicators under this Condition of Certification would apply irrespective of the form or medium in which the communication is made. Developers must not prohibit or restrict communications whether written, oral, electronic or by any other method if they concern protected communications, unless permitted otherwise by this Condition of

[57] IOM (Institute of Medicine), *Health IT and Patient Safety: Building Safer Systems for Better Care* (2012). Available at *http://www.nationalacademies.org/hmd/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx.*

[58] *Id,* 195.

[59] *Ibid.*

[60] *Ibid.*

[61] *Ibid.*

[62] *See* Kathy Kenyon, *Overcoming Contractual Barriers to EHR Research,* Health Affairs Blog (October 14, 2015). Available at *http://healthaffairs.org/blog/2015/10/14/overcoming-contractual-barriers-to-ehr-research/.*

[63] *See* Hardeep Singh, David C. Classen, and Dean F. Sittig, *Creating an Oversight Infrastructure* for *Electronic Health Record-Related Patient Safety Hazards,* 7(4) Journal of Patient Safety 169 (2011). Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3677059/.*

[64] Kathy Kenyon, *Overcoming Contractual Barriers to EHR Research,* Health Affairs Blog (October 14, 2015). Available at *http://healthaffairs.org/blog/2015/10/14/overcoming-contractual-barriers-to-ehr-research/.*

[65] HELP 6/10/15 pg 12; Available at *https://www.gpo.gov/fdsys/pkg/CHRG-114shrg25971/pdf/CHRG-114shrg25971.pdf.*

[66] HELP 3/17/15 pg 47; Available at *https://www.gpo.gov/fdsys/pkg/CHRG-114shrg93864/pdf/CHRG-114shrg93864.pdf.*

[67] HELP 7/23/15 pg 13, pg 27; Available at *https://www.help.senate.gov/hearings/achieving-the-promise-of-health-information-technology-information-blocking-and-potential-solutions.*

[68] HELP 7/23/15 pg 38; Available at *https://www.help.senate.gov/hearings/achieving-the-promise-of-health-information-technology-information-blocking-and-potential-solutions.*

[69] Energy and Commerce 7/17/14 pg 35; Available at *http://docs.house.gov/meetings/IF/IF16/20140717/102509/HHRG-113-IF16-20140717-SD008.pdf.*

[70] D Tahir, *POLITICO Investigation: EHR gag clauses exist—and, critics say, threaten safety,* Politico, August 27, 2015.

[71] *Ibid.*

[72] *Ibid.*

Certification. Similarly, this Condition of Certification does not impose any limit on the identity of the communicators that are able to benefit from the protection afforded, except that employees and contractors of a health IT developer may be treated differently when making communications that are not afforded unqualified protection under § 170.403(a)(2)(i). This Condition of Certification is not limited to communications by health IT customers (*e.g.,* providers) who have contracts with health IT developers. Entities or individuals who enter into agreements with a developer in connection with the developer's health IT—for example, a data analytics vendor who is required to sign a non-disclosure agreement before being granted access to the developer's health IT—would also be covered by the protection afforded to communicators under this Condition of Certification. Patients, health IT researchers, industry groups, and health information exchanges would be able to make protected communications about the health IT free of impermissible prohibitions or restrictions. Similarly, the Condition of Certification would also extend to potential customers of health IT who are provided with product or software demonstrations, irrespective of whether they proceed with the acquisition of the technology. Examples of other protected communications include, but are not limited to:

- A post made to an online forum;
- the sharing of screenshots, subject to certain proposed restrictions on their general publication;
- an unattributed written review by a health IT user;
- a quote given by a health care executive to a journalist;
- a presentation given at a trade show;
- a social media post;
- a product review posted on a video-sharing service such as YouTube;
- the statements and conclusions made in a peer-reviewed journal; and
- private communications made between health IT customers about the health IT.

ii. Protected Subject Areas

The Cures Act (and § 170.403(a)(1)) identifies a list of subject areas about which developers cannot prohibit or restrict communications. These subject areas address health IT performance and usability, health IT security, and the business practices related to exchanging EHI. For the reasons discussed below, we propose that the terms used to describe the subject areas should be construed broadly, consistent with the scope of communications that Congress specified in the Act. We encourage comment on whether the types of subject matter we identify below are adequate to protect the full range of communications contemplated by the Cures Act.

(A) Usability of Health Information Technology

The term ''usability'' is not defined in the Cures Act nor in any other relevant statutory provisions. In the National Institute of Standards and Technology (NIST) Usability Initiative, NIST describes ''usability'' of health IT by referencing the ISO [73] standard, ISO9241: Usability is ''the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.'' [74] Separately, HIMSS [75] has recognized the following principles of software usability: Simplicity; Naturalness; Consistency; Forgiveness and Feedback; Effective Use of Language; Efficient Interactions; Effective Information Presentation; Preservation of Context; and Minimize Cognitive Load.[76] As these organizations have expressed, there are a multitude of factors that contribute to any judgment about ''usability,'' and any assessment about the usability of health IT should appropriately rest on the factors contributing to the effectiveness, efficiency, and performance offered. As such, we propose that the ''usability'' of health IT be construed broadly to include both an overall judgment on the ''usability'' of a particular health IT product, as well as any factor that contributes to usability. Factors of usability that could be the subject of protected communications include, but are not limited to: The user interface (*i.e.,* what a user sees on the screen, such as layout, controls, graphics and navigational elements); ease of use (*e.g.,* how many clicks); how the technology supports users' workflows; the organization of information; cognitive burden; cognitive support; error tolerance; clinical decision support; alerts; error handling; customizability; use of templates; mandatory data elements; the use of text fields; and customer support.

(B) Interoperability of Health Information Technology

Section 3000(9) of the PHSA, as amended by the Cures Act, provides a definition of ''interoperability'' that describes a type of health IT that demonstrates the necessary capabilities to be interoperable. For the purposes of this Condition of Certification, we propose that protected communications regarding the ''interoperability of health IT'' would include communications about whether a health IT product and associated developer business practices meet the interoperability definition described in section 3000(9) of the PHSA, including communications about aspects of the technology or developer that fall short of the expectations found in that definition. This will include communications about the interoperability capabilities of health IT and the practices of a health IT developer that may inhibit the access, exchange, or use of EHI, including information blocking.

(C) Security of Health IT

The security of health information technology is primarily addressed under the HIPAA Security Rule,[77] which establishes national standards to protect individuals' electronic protected health information (ePHI) that is created, received, maintained, or transmitted by a covered entity or business associate. Covered entities and business associates must ensure the confidentiality, integrity, and availability of all such ePHI; protect against any reasonably anticipated threats or hazards to the security or integrity of such information; and protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under the HIPAA Privacy Rule.[78] HIPAA requires that health IT developers, to the extent that they are business associates of HIPAA-covered entities, implement appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of ePHI.

We propose that the matters that fall within the topic of health IT security should be broadly construed to include any safeguards, whether or not required by the Security Rule, that may be implemented (or not implemented) by a developer to ensure the confidentiality,

[73] The International Organization for Standardization (ISO) is an international standard-setting organization that develops, publishes, and promotes proprietary, industrial, and commercial standards. For more information see *https://www.iso.org/home.html.*

[74] *See https://www.nist.gov/programs-projects/health-it-usability.*

[75] The Healthcare Information and Management Systems Society (HIMSS) is a not-for-profit organization that promotes the use of information technology in health care. For more information, see *http://www.himss.org/.*

[76] *See http://www.himss.org/what-ehr-usability.*

[77] 45 CFR part 160 and subparts A and C of part 164.

[78] 45 CFR part 160 and subparts A and E of part 164.

integrity, and security of the wider set of EHI (including ePHI), together with the health IT product's performance regarding security. For example, a developer may not prohibit or restrict a potential communicator from communicating about, without limitation:

- The approach to security adopted for the health IT at issue (*e.g.,* architectural approach or authentication methodology);
- the resilience of the health IT;
- identified security flaws in the developer's health IT; or
- the response to cyber threats or security breaches by the developer.

(D) User Experiences

The phrase ''user experience'' is not defined in the Cures Act nor in any other relevant statutory provisions. We propose to afford these terms their ordinary meaning. To qualify as a ''user experience,'' the experience must be one that is had by a user of health IT. However, beyond this, we do not propose to qualify the types of experiences that would receive protection under the Condition on the basis of the ''user experience'' subject area. This reflects the great variety of experiences that users may have with health IT and the often subjective nature of such experiences. Thus, we believe that if the user had the experience, the experience is relevant.

To illustrate the breadth of potential user experiences that would be protected by this Condition of Certification, we propose that communications about ''relevant information regarding users' experiences when using the health IT'' would encompass, for example, communications and information about a person or organization's experience acquiring, implementing, using, or otherwise interacting with health IT. This includes experiences associated with the use of the health IT in the delivery of health care, together with administrative functions performed using the health IT. User experiences would also include the experiences associated with configuring and using the technology throughout implementation, training, and in practice. Further, user experiences would include patients' and consumers' user experiences with consumer apps, patient portals, and other consumer-facing technologies. To be clear, a ''relevant user experience'' includes any aspect of the health IT user experience that could positively or negatively impact the effectiveness or performance of the health IT.

(E) Manner in Which a User Has Used Health IT

We propose that protected communications regarding the ''manner in which a user has used health IT'' would encompass any information related to how the health IT has been used in practice. This subject area largely overlaps with the matters covered under the ''user experience'' subject area but may include additional perspectives or details beyond those experienced by a user of health IT. Types of information that would fall within this subject area include but are not limited to:

- Information about a work-around implemented to overcome an issue in the health IT;
- customizations built on top of core health IT functionality;
- the specific conditions under which a user used the health IT, such as information about constraints imposed on health IT functionality due to implementation decisions; and
- information about the ways in which health IT could not be used or did not function as was represented by the developer.

(F) Business Practices Related to Exchange

We propose that the subject matter of ''developer business practices related to exchanging electronic health information'' should be broadly construed to include developer policies and practices that facilitate the exchange of electronic health information, and developer policies and practices that impact the ability of health IT to exchange health information. We further propose That the exchange of electronic health information encompasses the appropriate and timely sharing of electronic health information.

We propose that protected communications include, but are not limited to:

- The costs charged by a developer for products or services that support the exchange of electronic health information (*e.g.,* interface costs, API licensing fees and royalties, maintenance and subscription fees, transaction or usage-based costs for exchanging information);
- the timeframes and terms on which developers will or will not enable connections and facilitate exchange with other technologies, individuals, or entities, including other health IT developers, exchanges, and networks;
- the developer's approach to participation in health information exchanges and/or networks;
- the developer's licensing practices and terms as it relates to making available APIs and other aspects of its technology that enable the development and deployment of interoperable products and services; and
- the developer's approach to creating interfaces with third-party products or services, including whether connections are treated as ''one off'' customizations, or whether similar types of connections can be implemented at a reduced cost.

Importantly, we further propose that information regarding business practices related to exchanging electronic health information would include information about the switching costs imposed by a developer, as we are aware that the cost of switching health IT is a significant factor impacting health care providers adopting the most exchange-friendly health IT products that are available.

iii. Meaning of ''Prohibit or Restrict''

The terms ''prohibit'' and ''restrict'' are not defined in the Cures Act or in any other relevant statutory provisions. As discussed in detail below, communications can be prohibited or restricted through contractual terms or agreements (*e.g.,* non-disclosure agreements, non-disparagement clauses) as well as through conduct, including punitive or retaliatory business practices that are designed to create powerful disincentives to engaging in communications about developers or their products. Therefore, we propose that this Condition of Certification would not be limited to only formal prohibitions or restrictions (such as by means of contracts or agreements) and would encompass any conduct by a developer that would be likely to restrict a communication or class of communications protected by this Condition, as discussed in detail below.

The conduct in question must have some nexus to the making of a protected communication or an attempted or contemplated protected communication. That is, conduct by a developer that may be perceived as intimidating or punitive would not implicate this Condition of Certification unless that conduct was designed to directly or indirectly influence the making of a protected communication. Similarly, health IT contracts may include terms that govern the manner in which the parties conduct themselves, and those terms would not implicate this Condition of Certification unless the operative effect of a term was to restrict or prohibit a protected communication. For abundant clarity, we note that the fact that a customer's health IT product is not performing in the manner the customer expected, or in the manner

that the developer promised, would not, in itself be evidence that the developer is engaging in conduct that restricts or prohibits a protected communication. Rather, a nexus must exist between the alleged poor performance and the making of (or attempting or contemplating to make) a protected communication.

We note that contractual prohibitions or restrictions on communications can, in limited circumstances, be legitimate and serve an important role in protecting proprietary information and intellectual property that are essential for health IT developers to innovate and compete. On this basis, we propose to permit certain types of prohibitions and restrictions, subject to strict conditions to ensure that they are narrowly tailored and do not restrict protected communications. These permitted prohibitions and restrictions are discussed in section VII.B.3.b.v below.

(A) Prohibitions or Restrictions Arising by Way of Contract

The principal way that health IT developers can control the disclosure of information about their health IT is through contractual prohibitions or restrictions. Such prohibitions or restrictions can arise in contractual provisions that address, for example, confidentiality obligations, intellectual property protections, hold-harmless requirements, nondisclosure obligations, non-compete obligations, and publicity rights.

There are different ways that contractual prohibitions or restrictions arise. In some instances a contractual prohibition or restriction will be expressed, and the precise nature and scope of the prohibition or restriction will be explicit from the face of the contract or agreement. For example, a contract will say that the health IT customer must not disclose screenshots of the health IT. However, more often, a contract will impose prohibitions or restrictions in less precise terms. For example, a health IT contract might use broad language when describing the information or materials that customers and users are forbidden from disclosing pursuant to a confidentiality clause, casting a vague net over the developer's ''proprietary'' information and purporting to cover information that may be neither confidential, secret, nor protected by law. A contract does not need to expressly prohibit or restrict a protected communication in order to have the effect of prohibiting or restricting that protected communication. The use of broad or vague language that obfuscates the types of communications that can and cannot be made may be treated as a prohibition or restriction if it has the effect of restricting legitimate communications about health IT.

Restrictions and prohibitions found in contracts used by developers to sell or license their health IT products can apply to customers directly and can require that the customer ''flow-down'' obligations onto the customer's employees, contractors, and other individuals or entities that use or work with the developer's health IT. Such contract provisions would not comply with this Condition of Certification if they prohibit or restrict protected communications. Prohibitions or restrictions on communications can also be found in separate nondisclosure agreements (NDAs) that developers require their customers—and in some instances the users of the health IT—to enter into in order to receive or access the health IT. We propose that such agreements are covered by this Condition of Certification. Finally, health IT developers typically may require third-party contractors used by their customers (such as a data analytics vendor engaged by a health care provider to analyze the provider's data) to enter into a NDA with the developer before commencing their contract activities. In some extreme cases, the employees of these third-party contractors are required to sign NDAs in their personal capacities. These NDAs typically include obligations that prohibit or restrict communications about the developer's health IT products, and we propose that any such prohibitions or restrictions within the context of protected communications as defined here would be subject to this Condition of Certification.

(B) Prohibitions or Restrictions That Arise by Way of Conduct

We are aware that some health IT developers engage in conduct that has the effect of prohibiting or restricting protected communications. This conduct may arise despite the developer's contract and/or business associate agreement being silent on, or even expressly permitting, the protected communication. The effect of such conduct can be significant, as health care providers are dependent on their health IT developer in order to receive critical software updates or other maintenance services, and sometimes have little bargaining power. Similarly, a third-party developer is dependent on a health IT developer's authorization in order to perform work in connection with the developer's health IT.

We propose that conduct that has the effect of prohibiting or restricting a protected communication would be subject to this Condition of Certification. We emphasize that, as discussed above, the conduct in question must have some nexus to the making of a protected communication or an attempted or contemplated protected communication. As such, developer conduct that was alleged to be intimidating, or health IT performance that was perceived to be substandard, would not, in and of itself, implicate this Condition of Certification unless there was some nexus between the conduct or performance issue and the making of (or attempting or threatening to make) a protected communication. Examples of conduct that could implicate this Condition of Certification include, but are not limited to:

- Taking steps to enforce, including by threatening to enforce, a right arising under contract that contravenes this Condition of Certification.
- Taking steps to enforce, including by threatening to enforce, a legal right that purports to prohibit or restrict a protected communication. This would include, for example, the making of threats, such as via a cease and desist letter, to a researcher who has made a protected communication.
- Employing a technological measure (within the meaning of 17 U.S.C. 1201) that a user would have to circumvent in order to make a protected communication, for example, a technological measure that a health IT user would need to circumvent in order to take a screenshot of the developer's health IT.
- Discouraging the making of protected communications by:
  - Making threats against a health care customer (*e.g.,* by threatening to withhold the latest version of the developer's software) in response to the customer making or attempting to make a protected communication.
  - Taking retaliatory action against a person or entity that has made a protected communication (*e.g.,* withholding support, delaying the provider's adoption of a new software release, or removing a provider from the developer's ''preferred customer'' list).
- Having policies that disadvantage persons or entities that make protected communications (*e.g.,* a policy that bars a provider from qualifying for the developer's ''preferred customer'' list if it shares screenshots in a manner protected by this Condition of Certification).
- Refusing to publish—or refusing to remove or delete—protected communications made in an online forum that the developer moderates or controls.

• Causing the removal or deletion of a protected communication from any publication (*e.g.,* a YouTube Copyright Take-down Notice that does not raise a legitimate copyright claim).

iv. Communications With Unqualified Protection

We propose, and discuss below, a narrow class of communications—consisting of five specific types of communications—that would receive unqualified protection from developer prohibitions or restrictions. With respect to communications with unqualified protection, a developer would be prohibited from imposing *any* prohibition or restriction. As discussed below, we propose that this narrow class of communications warrants unqualified protection because of the strength of the public policy interest being advanced by the communication and/or the sensitivity with which the identified recipient treats, and implements safeguards to protect the confidentiality and security of, the information received. A developer that imposes a prohibition or restriction on a communication with unqualified protection would fail the first part of the two-part test for allowable prohibitions or restrictions, and as such would contravene the Condition of Certification.

(A) Disclosures Required by Law

We propose that where a communication relates to subject areas enumerated in § 170.403(a)(1) and there are federal, state, or local laws that would require the disclosure of information related to health IT, developers must not prohibit or restrict in any way protected communications made in compliance with those laws. We note that we expect that most health IT contracts would allow for, or at the very least not prohibit or restrict, any communication or disclosure that is required by law, such as responding to a court or Congressional subpoena, or a valid warrant presented by law enforcement. We further propose that if required by law, a potential communicator should not have to delay any protected communication under this Condition of Certification. Furthermore, we propose that the reasonable limitations and prohibitions that are discussed below and permitted by § 170.403(a)(2) do *not* apply to these types of protected communications.

(B) Communicating Information About Adverse Events, Hazards, and Other Unsafe Conditions to Government Agencies, Health Care Accreditation Organizations, and Patient Safety Organizations

It is well established that there is a strong public interest in allowing open communication of information regarding health care hazards, adverse events, and unsafe conditions. Given the central role played by health IT in the delivery of care, information about health IT is a critical component of any investigation into the cause of hazards, adverse events, or unsafe conditions. On the basis of this public policy interest alone, we propose there is an overwhelming interest in ensuring that all communications about health IT that are necessary to identify patient safety risks, and to make health IT safer, not be encumbered by prohibitions or restrictions imposed by health IT developers that may affect the extent or timeliness of communications. In addition to the public policy interest in promoting uninhibited communications about health IT safety, the recognized communication channels for adverse events, hazards, and unsafe conditions provide protections that help ensure that any disclosures made are appropriately handled and kept confidential and secure. Indeed, the class of recipients to which the information can be communicated under this category of communications with unqualified protection should provide health IT developers with comfort that there is very little risk of such communications prejudicing the developer's intellectual property rights. For example, government agencies impose appropriate controls on information they receive, mitigating any risk that developers may feel arises from the disclosure of information about their health IT. Similarly, accrediting bodies for health care delivery observe strict confidentiality policies for information received or developed during the accreditation process and in connection with complaints received.

Finally, the Patient Safety and Quality Improvement Act of 2005 (PSQIA) [79] provides for privilege and confidentiality protections for information that meets the definition of patient safety work product (PSWP). This means that PSWP may only be disclosed as permitted by the PSQIA and its implementing regulations. We clarify that to the extent activities are conducted in accordance with the PSQIA, its implementing regulation, and section 4005(c) of the Cures Act, no such activities shall be construed as constituting restrictions or prohibitions that contravene this Condition of Certification.

We understand that the nature of the information about health IT that would ordinarily be disclosed by a health care provider when reporting an adverse event, hazard, or unsafe conditions to government agencies, health care accreditation organizations, and patient safety organizations, would not ordinarily contain intellectual property or trade secrets. Notwithstanding this, in light of the public policy interest and established reporting mechanisms described above, we do not consider the potential inclusion of intellectual property or trade secrets in the communication should prohibit or restrict a health care provider from making a complete and timely report. For example, proposed § 170.403(a)(2)(ii)(D) permits developers to impose certain restrictions on the general publication of screenshots, but we do not consider that such restrictions should be permitted when the communication is made for one of the purposes, and to one of the recipients, identified in § 170.403(a)(2)(i)(B).

We seek comment on whether the unqualified protection afforded to communications made to a patient safety organizations about adverse events, hazards, and other unsafe conditions should be limited. Specifically, we seek comment on whether the unqualified protection should be limited by the nature of the patient safety organization to which a communication can be made, or the nature of the communication that can made—such as limiting to only material that was created as PSWP.

(C) Communicating Information About Cybersecurity Threats and Incidents to Government Agencies

We propose that if health IT developers were to impose prohibitions or restrictions on the ability of any person or entity to communicate information about cybersecurity threats and incidents to government agencies, such conduct would not comply with this Condition of Certification. Government agencies such as the United States Computer Emergency Readiness Team (US–CERT) respond to and protect both the government and private industry from cyber threats. Their work helps protect the entire health care system from cybersecurity threats and relies on the timely reporting of security issues and vulnerabilities by health care

[79] Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21–b–26 (Pub. L. 109–41).

providers and health IT users. These agencies impose appropriate controls on information they receive, which mitigates any risk that developers may feel arises from the disclosure of information about their health IT. The US–CERT, for example, provides secure forms for such reporting, and we are confident that reporting security incident information to US–CERT and other government agencies would be unlikely to pose any threat to health IT developer intellectual property or trade secrets. Additionally, the information likely reported regarding such an incident would generally not reveal trade secrets. Where circumstances may require collection of more sensitive and confidential information related to a developer's intellectual property, we believe that appropriate protections would likely apply and that the public benefit of thoroughly investigating and addressing cybersecurity issues outweighs any potential harm.

Communications about security issues related to health IT may alert nefarious individuals or entities to the existence of a security vulnerability which could be exploited before a developer has time to fix the vulnerability. However, we propose that this concern must be balanced against the imperative of ensuring that health IT customers are aware of security vulnerabilities so that they can respond by deploying reactive measures independent of the developer, such as ceasing health information exchange with a compromised system. We seek comment on whether it would be reasonable to permit health IT developers to impose limited restrictions on communications about security issues so as to safeguard the confidentiality, integrity, and security of eHI. For example, should health IT developers be permitted to require that health IT users notify the developer about the existence of a security vulnerability prior to, or simultaneously with, any communication about the issue to a government agency?

(D) Communicating Information About Information Blocking and Other Unlawful Practices to a Government Agency

As in the circumstances described above, we believe that the public benefit associated with the communication of information to government agencies on information blocking, or any other unlawful practice, outweighs any concerns developers might have about the disclosure of information about their health IT. We believe that reporting information blocking, as well as other unlawful practices, to a government agency would not cause an undue threat to a health IT developer's intellectual property or trade secrets. Generally speaking, agencies collecting reports would protect all information received and keep it confidential to the extent permitted by law.

(E) Communicating Information About a Health IT Developer's Failure To Comply With a Condition of Certification or Other Program Requirement

We propose that the benefits to the public and to users of health IT of communicating information about a health IT developer's failure to comply with a Condition of Certification or other Program requirement (45 CFR part 170) justify prohibiting developers of health IT from placing any restrictions on such protected communications. Information regarding the failure of a health IT product to meet any Condition of Certification or other Program requirement is vital to the effective performance and integrity of the Program, which certifies that health IT functions consistent with its certification. While the current procedures for reporting issues with certified health IT encourage providers to contact developers in the first instance to address certification issues, users of health IT should not hesitate to contact ONC-Authorized Certification Bodies (ONC–ACBs), or ONC itself, if the developer does not provide an appropriate response, or the matter is of a nature that should be immediately reported to an ONC–ACB or to ONC.

v. Permitted Prohibitions and Restrictions

We propose that, *except for communications with unqualified protection discussed above and enumerated in § 170.403(a)(2)(i),* health IT developers would be permitted to impose certain narrow kinds of prohibitions and restrictions discussed below and specified in § 170.403(a)(2)(ii). We believe this policy strikes a reasonable balance between the need to promote open communication about health IT and related business practices and the need to protect the legitimate interests of health IT developers and other entities. Specifically, with the exception of communications with unqualified protection, developers would be permitted to prohibit or restrict the following communications, subject to certain conditions:

- Communications of their own employees;
- Disclosure of non-user-facing aspects of the software;
- Certain communications that would infringe the developer's or another person's intellectual property rights;
- Publication of screenshots in very narrow circumstances; and
- Communications of information that a person or entity knows only because of their participation in developer-led product development and testing.

As discussed in detail in the sections that follow, the proposed Condition of Certification carefully delineates the circumstances under which these types of prohibitions and restrictions would be permitted, including certain associated conditions that developers would be required to meet. To be clear, any prohibition or restriction not expressly permitted would violate the Condition. Additionally, it would be the developer's burden to demonstrate to the satisfaction of ONC that the developer has met all associated requirements. Further, as an additional safeguard, we propose that where a developer seeks to avail itself of one of the permitted types of prohibitions or restrictions, the developer must ensure that potential communicators are clearly and explicitly notified about the information and material that can be communicated, and that which cannot. We propose this would mean that the language of health IT contracts must be precise and specific. Contractual provisions or public statements that support a permitted prohibition or restriction on communication should be very specific about the rights and obligations of the potential communicator. Contract terms that are vague and cannot be readily understood by a reasonable health IT customer will not benefit from the qualifications to this Condition of Certification outlined below.

(A) Developer Employees and Contractors

We recognize that health IT developer employees, together with the entities and individuals who are contracted by health IT developers to deliver products and/or services (such as consultants), may be exposed to highly sensitive, proprietary, and valuable information in the course of performing their duties. We also recognize that the proper functioning of a workforce depends, at least in part, on the ability of an employer to regulate how and when the organization communicates information to the public, and that employees owe confidentiality obligations to their employers. We propose that on this basis, developers are permitted to impose prohibitions or restrictions on the communications of employees and

contractors to the extent that those communications fall outside of the class of communications with unqualified protection as discussed above.

(B) Non-User-Facing Aspects of Health IT

The purpose of this Condition of Certification is to ensure that health IT users and other potential communicators are not restrained in their ability to communicate—publicly or privately—about certain protected subject areas. We propose that this purpose can generally be achieved without communicators disclosing information about those parts of health IT that are legally protected trade secrets. As such, we propose this Condition of Certification will permit health IT developers to impose prohibitions and restrictions on communications that are not communications with unqualified protection to the extent necessary to ensure that communications do not disclose ''non-user-facing aspects of health IT.''

A ''non-user-facing aspect of health IT'' is, for the purpose of this Condition of Certification, an aspect of health IT that is not a ''user-facing aspect of health IT.'' A ''user-facing aspect of health IT'' means those aspects of health IT that that are disclosed and evident to anyone running, using, or observing the operation of health IT. That is, a user-facing aspect of health IT comprises those aspects of the health IT that are manifest in how the health IT software works. User-facing aspects of health IT include the design concepts and functionality that is readily ascertainable from the health IT's user interface and screen display. They do not include those parts of the health IT that are not exposed to persons running, using, or observing the operation of the health IT. We propose that non-user-facing aspects of health IT would include source and object code, software documentation, design specifications, flowcharts, and file and data formats. We welcome comments on whether these and other aspects of health IT should be treated as not being user-facing.

For clarity, we note that the terminology of ''user-facing aspects of health IT'' is not intended to afford only health IT users with specific protections against developer prohibitions or restrictions on communications. Rather, the terminology is agnostic as to the identity of the communicator and is instead focused on describing those aspects of health IT that are readily ascertainable from the health IT's user interface and screen display. Numerous other potential communicators will also be exposed to ''user-facing aspects of health IT,'' such as third-party contractors, health information exchange organizations, recipients of a software demonstration, and trade groups or researchers that observe the operation of health IT in the field.

We propose that this approach reasonably implements the Cures Act, which, in direct response to strict confidentiality obligations, broad intellectual property clauses, and non-disclosure provisions in EHR contracts, identified a list of protected subject areas for disclosure (enumerated at section 3001(c)(5)(D)(iii) of the PHSA) that largely targeted the aspects of health IT that are apparent to, and known by, individuals and entities that use or interact with health IT. We propose that if a health IT user were prohibited from describing the user-facing aspects of their health IT product, they could not sensibly communicate useful information about the usability or interoperability of the product, or their experiences as a health IT user. These subject areas are fundamentally tied to the way that the health IT product works, its design, and its functionality.

Protecting the communication of ''user-facing aspects of health IT'' is also consistent with the treatment of software products under trade secret law, where the public-facing aspects of software products are not generally considered secret because they are evident to anyone running the software program. Moreover, this approach is appropriate given the manner in which health IT is deployed and used by health IT customers. Unlike software products that are deployed and used in a cloistered setting where access to the software is highly restricted, health IT is typically deployed in a setting in which the operation of the health IT can be readily observed by a wide range of persons. Health IT used in a physician's consulting room can be observed by the patient. Health IT deployed in a hospital can be observed by numerous individuals in addition to those who are ''authorized users'' of the health IT system, including, for example, the patient, the patient's family, volunteer staff, law enforcement, and clergy. As such, because health IT is of a nature that license terms or nondisclosure obligations do not act as a genuine control over the disclosure of those aspects of the software that are ''user-facing,'' communications about such aspects should be afforded protection from developer prohibitions and restrictions under this proposed Condition of Certification.

(C) Intellectual Property

Many aspects of health IT—including software and documentation—will contain intellectual property that belongs to the health IT developer (or a third party) and is protected by law. Health IT products may have portions in which copyrighted works exist, or that are subject to patent protection. As in other technology sectors, health IT developers place a high value on their intellectual property and go to significant lengths to protect it, including intellectual property provisions in their health IT contracts.

This Condition of Certification is not intended to operate as a *de facto* license for health IT users and others to act in any way that might infringe the legitimate intellectual property rights of developers. Indeed, we propose that health IT developers are permitted to prohibit or restrict communications that would infringe their intellectual property rights so long as the communication in question is not a communication with unqualified protection. However, any prohibition and restriction imposed by a developer must be no broader than legally permissible and reasonably necessary to protect the developer's legitimate intellectual property interests. We are aware that some health IT contracts contain broad intellectual property provisions (and related terms, such as nondisclosure provisions) that purport to prevent health IT customers and users from using copyright material in ways that are lawful. On this basis, while we are providing an exception for the protection of intellectual property interests, we want to clarify that under this Condition of Certification health IT developers are not permitted to prohibit or restrict, or purport to prohibit or restrict, communications that would be a ''fair use'' of any copyright work comprised in the developer's health IT. That is, a developer is not permitted to prohibit or restrict communications under the guise of copyright protection (or under the guise of a confidentiality or non-disclosure obligation) when the communication in question makes a use of the copyright material in a way that would qualify that use as a ''fair use.'' [80]

We welcome comments on whether an appropriate balance has been struck between protecting legitimate intellectual property rights of developers and ensuring that health IT customers, users, researchers, and other stakeholders who use and work with health IT can openly discuss and share their experiences and other relevant

[80] *See* 17 U.S.C. 107.

information about the performance of health IT.

(D) Faithful Reproductions of Health IT Screenshots

We propose that health IT developers generally would not be permitted to prohibit or restrict communications that disclose screenshots of the developer's health IT. We consider screen displays an essential component of health IT performance and usability, and their reproduction may be necessary in order for a health IT user or other health IT stakeholder to properly make communications about the subject matters enumerated in § 170.403(a)(1). We acknowledge that some health IT developers have historically and aggressively sought to prohibit the disclosure of such communications. We consider that developers may benefit from screen displays being faithfully reproduced so that health IT users and other stakeholders can form an objective opinion on any question raised about usability in communications protected by this proposed Condition of Certification. Moreover, we consider that the reproduction of screenshots in connection with the making of a communication protected by this Condition of Certification would ordinarily represent a ''fair use'' of any copyright subsisting in the screen display, and developers should not impose prohibitions or restrictions that would limit that fair use.

Notwithstanding the above, we propose to permit certain prohibitions and restrictions on the communication of screenshots. Except in connection with communications with unqualified protection, developers would be permitted to impose certain restrictions on the disclosure of screenshots, as described below.

In order to ensure that disclosures of screenshots are reasonable and represent a faithful reproduction of the developer's screen design and health IT, we propose that developers would be permitted to prevent communicators from altering screenshots, other than to annotate the screenshot or to resize it for the purpose of publication. We consider this a reasonable limitation on the disclosure of screenshots and one that would help developers' health IT avoid being misrepresented by communicators seeking to make a communication protected by this proposed Condition of Certification.

We also propose that health IT developers could impose restrictions on the disclosure of a screenshot on the basis that it would infringe third-party intellectual property rights (on their behalf or as required by license). However, to take advantage of this exception, the developer would need to first put all potential communicators on sufficient written notice of those parts of the screen display that contain trade secrets or intellectual property rights and cannot be communicated, and would still need to allow communicators to communicate redacted versions of screenshots that do not reproduce those parts.

Finally, we also recognize that health IT developers may have obligations under HIPAA as a business associate and that it would be reasonable for developers to impose restrictions on the communication of screenshots that contain protected health information, provided that developers permit the communication of screenshots that have been redacted to conceal protected health information, or the relevant individual's consent or authorization had been obtained.

(E) Testing and Development

We are aware that some health IT developers expose aspects of their health IT to health care providers and others for the purpose of testing and development prior to a product's ''general availability'' release. Such disclosures may relate to beta releases that are shared with certain customers for testing prior to the software being made generally available to the market, or may be made as part of a joint-venture or cooperative development process. In these circumstances, we propose that a health IT developer would be justified in keeping information about its health IT confidential, and we do not intend that the protection afforded to communicators under this Condition of Certification would allow disclosures of this information. This permitted prohibition or restriction would allow developers to seek appropriate intellectual property protection and freely discuss novel, ''unreleased'' product features with their customer base, which has significant public policy benefits for research and innovation in the health IT industry.

As with the other allowable restrictions listed above, we propose that this permitted restriction would be limited and does not apply to communications which are communications with unqualified protection as described above and specified in § 170.403(a)(2)(i). For example, information that is learned as part of development and testing, such as the hard-coding of test procedure processes that raise serious patient safety concerns, could be communicated for one of the limited purposes specified in § 170.403(a)(2)(i) if the software is certified or released to market. We propose that this permitted restriction would also not apply to communications about the released version of the health IT once the health IT has been released to market or has been certified, provided that the communications otherwise meet all other requirements to be afforded protection under this Condition of Certification and the information communicated could be discovered by any ordinary user of the health IT.

For example, a health IT developer and a large health system enter into an agreement for members of the health IT developer's engineering team to work with members of the health system's clinical team to develop a customization for the system's use of the developer's EHR. In order to properly protect any intellectual property rights, or proprietary information, arising from this work, the developer and health system enter into a contract which imposes on the system and affected members of its clinical team strict nondisclosure related to testing and development of the health IT. This would be reasonable and would not contravene this Condition of Certification, provided that: (1) The nondisclosure obligations were narrowly targeted toward the work product associated with the testing and development; and (2) the obligations ceased immediately upon any resultant software being deployed in the health system, to the extent that the information fell within one of the subject areas enumerated in § 170.403(a)(1) and would be apparent to an ordinary user of the health IT.

To ensure that this permitted prohibition/restriction is not abused, such as by maintaining a product in beta release for an indefinite or lengthy period of time, we request comment on whether we should limit the time this protection would apply for testing purposes. This could be no longer than a year after release of a product or update. We also request comment on whether we should set specific parameters for covered testing. For example, we note above our expectations that a product would be shared with *certain* customers for testing prior to the software being made *generally available* to the market. As such, for this permitted prohibition/restriction to apply, should we more specifically limit the extent a product can be distributed to customers for testing purposes?

c. Maintenance of Certification Requirements

We propose that to maintain compliance with this Condition of Certification a health IT developer must not establish or enforce any contract or agreement provision that contravenes this Condition of Certification. We are aware that some developers currently have in place health IT contracts that contain provisions that contravene this proposed Condition of Certification because they impose impermissible prohibitions or restrictions on communications. In some instances, the provisions in question will be expressly at odds with this Condition, imposing obligations on health IT customers, or creating rights in favor of the developer, that prohibit or restrict communications that are protected. In other instances, a contract will include a provision that contravenes this Condition because it has been drawn in such broad terms—such as an overly-expansive definition of confidential information—that a reasonable reader of the provision would consider the making of a communication protected by this Condition a breach of the contract.

Health IT contracts are typically for a significant duration—*e.g.,* 5 years or more—or include an automatic renewal whereby the then current terms roll over for any renewal period. The implementation of this proposed Condition of Certification cannot therefore wait until health IT contracts that contravene this Condition expire in the ordinary course. As such, we are requiring that health IT developers take immediate steps to become in compliance with this Condition of Certification.

We propose that a health IT developer must notify all customers and those with which it has contracts/agreements, within six months of the effective date of a subsequent final rule for this proposed rule, that any communication or contract/agreement provision that contravenes this Condition of Certification will not be enforced by the health IT developer. Further, we propose that this notice would need to be provided annually up to and until the health IT developer amends the contract or agreement to remove or make void any contractual provision that contravenes this Condition of Certification. We further propose as a Maintenance of Certification requirement in § 170.405(b)(2) that health IT developers must amend their contracts or agreements to remove or make void any provisions that contravene the Condition of Certification within a reasonable period of time, but not later than two years from the effective date of a subsequent final rule for this proposed rule.

We believe this is an appropriate approach as we understand that health IT developers are in regular contact with their customers, and so the provision of a notice that satisfies this requirement should not present an undue burden for a developer. We would also expect that developers have kept good records of nondisclosure agreements that they have entered into with other organizations or individuals, such as third-party developers, and can communicate with those organizations or individuals as necessary to satisfy this requirement. In the event that a health IT developer cannot, despite all reasonable efforts, locate an entity or individual that previously entered into an agreement with the developer that prohibits or restricts communications protected by this Condition, the developer would not be in contravention of this Condition so long as it takes no step to enforce the prohibition or restriction. For clarity, we do not propose that health IT developers be required to furnish to ONC or their ONC–ACB copies of notices made to customers, or copies of contracts or agreements revised, in satisfaction of this Maintenance of Certification requirement, although those communications may be requested by ONC or an ONC–ACB in the usual course of business. To this point, under the ''Enforcement'' section of this proposed rule (VII.D), we describe our general enforcement approach outlining a corrective action process for ONC to review instances where Conditions and Maintenance of Certification requirements are not being met by a health IT developer under the Program.

We note that another approach we considered proposing would have been to require that developers amend their current health IT contracts immediately. We have, however, relied on the proposed requirement that developers not enforce contractual terms that contravene this proposed Condition of Certification until they can amend their contracts in a reasonable period of time, but not later than two years from the effective date of a subsequent final rule for this proposed rule. We seek comment on whether this is an adequate approach to removing prohibitions and restrictions on protected communications and ensuring that health IT customers, users, researchers, and other stakeholders are aware of their right to engage in such communications notwithstanding existing contracts or agreements to the contrary.

4. Application Programming Interfaces

As a Condition of Certification (and Maintenance thereof) under the Program, the Cures Act requires health IT developers to publish APIs that allow ''health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law.'' The Cures Act's API Condition of Certification also states that a developer must, through an API, ''provide access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws.''

The Cures Act's API Condition of Certification includes several key phrases and requirements for health IT developers that go beyond just the technical functionality of the products they present for certification. In this section of the preamble we outline our proposals to implement the Cures Act's API Condition of Certification in order to provide compliance clarity for health IT developers.

These proposals include new standards, new implementation specifications, and a new certification criterion as well as detailed Conditions and Maintenance of Certification requirements. We also propose to modify the Base EHR definition. We note that health IT developers should also consider these proposals in the context of what could warrant review from an information blocking perspective in so far as action (or inaction) that would be inconsistent with this proposed rule's API Conditions and Maintenance of Certification requirements.

a. Statutory Interpretation and API Policy Principles

One of the most significant phrases in the Cures Act's API Condition of Certification concerns the deployment and use of APIs ''without special effort.'' Specifically, the Cures Act requires health IT developers to publish APIs and allow health information from such technology ''to be accessed, exchanged, and used without special effort.'' In this context, we interpret the ''effort'' exerted (*i.e.,* by whom) to be focused on the API users, which could include third-party software developers, the health care providers that acquired this API technology, and patients, health care providers, and payers that use apps/services that connect to API technology.

As we considered the meaning and context associated with the phrase ''without special effort'' and what

would make APIs included in certified health IT truly ''open,'' we focused on key attributes that could be used to refine our interpretation and guide our proposals. We interpret ''without special effort'' to require that APIs, and the health care ecosystem in which they are deployed, have three attributes: *Standardized, transparent,* and *pro-competitive.* Each of these attributes is briefly described in more detail below and all of our subsequent proposals address one or a combination of these attributes.

- *Standardized*—meaning that all health IT developers seeking certification would have to implement the same technical API capabilities in their products (using modern, computing standards such as RESTful interfaces and XML/JSON). Technical consistency and implementation predictability are fundamental to scale API-enabled interoperability and reduce the level of custom development and costs necessary to access, exchange, and use health information. Further, from a regulatory standpoint, health IT developers would gain certainty in regards to pre-certification testing requirements and post-certification ''real world testing'' expectations. Equally, from an industry standpoint, a consistent and predictable set of API functions would provide the health IT ecosystem with known technical requirements against which ''app'' developers and other innovative services can be built.
- *Transparent*—meaning that all health IT developers seeking certification would need to make the specific business and technical documentation necessary to interact with the APIs in production freely and publicly accessible. Such transparency and openness is commonplace in many other industries and has fueled innovation, growth, and competition.
- *Pro-competitive*—meaning that all health IT developers seeking certification would need to abide by business practices that promote the efficient access, exchange, and use of EHI to support a competitive marketplace that enhances consumer value and choice. Moreover, health care providers should have the sole authority and autonomy to unilaterally permit third-party software developers to connect to the API technology they have acquired. In other words, health IT developers must not interfere with a health care provider's use of their acquired API technology in any way, especially ways that would impact its equitable access and use based on (for example) another software developer's size, current client base, or business line. It also means that developers (together with health care providers that deploy APIs) are accountable to patients who, as consumers of health care services, have paid for their care and the information generated from such care. Thus, patients should be able to access their EHI via any API-enabled app they choose without special effort, including without incurring additional costs and without encountering access requirements that impede their ability to access their information in a persistent manner.

b. Key Terms

To clearly convey the stakeholders on which our proposals focus and are meant to support, we propose to use the following terms to reflect these meanings and/or roles:

- The term ''*API technology*'' (with a lowercase ''t'') generally refers to the capabilities of certified health IT that fulfill the API-focused certification criteria adopted or proposed for adoption at 45 CFR 170.315(g)(7) through (g)(11).
- ''*API Technology Supplier*'' refers to a health IT developer that creates the API technology that is presented for testing and certification to any of the certification criteria adopted or proposed for adoption at 45 CFR 170.315(g)(7) through (g)(11). We propose to adopt this term in § 170.102.
- ''*API Data Provider*'' refers to the organization that deploys the API technology created by the ''API Technology Supplier'' and provides access via the API technology to data it produces and electronically manages. In some cases, the API Data Provider may contract with the API Technology Supplier to perform the API deployment service on its behalf. However, in such circumstances, the API Data Provider retains control of what and how information is disclosed and so for the purposes of this definition is considered to be the entity that deploys the API technology. We propose to adopt this term in § 170.102.
- ''*API User*''—refers to persons and entities that use or create software applications that interact with the APIs developed by the ''API Technology Supplier'' and deployed by the ''API Data Provider.'' An API User includes, but is not limited to, third-party software developers, developers of software applications used by API Data Providers, patients, health care providers, and payers that use apps/services that connect to API technology. We propose to adopt this term in § 170.102.

We also use:

- The term ''*(g)(10)-certified API*'' for ease of reference throughout the preamble to refer to health IT certified to the certification criterion proposed for adoption in 45 CFR 170.315(g)(10).
- The term ''*app*'' for ease of reference to describe any type of software application that would be designed to interact with the (g)(10)-certified APIs. This generic term is meant to include, but not be limited to, a range of applications from mobile and browser-based to comprehensive business-to-business enterprise applications administered by third parties.

c. Proposed API Standards, Implementation Specifications, and Certification Criterion

APIs can be thought of as a set of commands, functions, protocols, and/or tools published by one software developer (''software developer A'') that enable other software developers (X, Y, and Z) to create programs and applications that interact with A's software without needing to know the ''internal'' workings of A's software. APIs can facilitate more seamless access to health information and it is important to note for context that ONC adopted three 2015 Edition certification criteria that specified API capabilities for Health IT Modules (criteria adopted in 45 CFR 170.315(g)(7), (g)(8), and (g)(9)). The following sections detail our proposals to adopt standards, implementation specifications, and a new API certification criterion. Together, these proposals account for the technical requirements we propose to associate with the Cures Act's API Condition of Certification and are reinforced through the condition's policy proposals.

i. Proposed Adoption of FHIR DSTU2 Standard

Overall, and on balance, we have structured our standards and implementation specifications proposals to best meet the health IT industry where it is most prepared to comply today. As a result, we propose to adopt the HL7® Fast Healthcare Interoperability Resources (FHIR®) standard as a foundational standard within our suite of proposals. Specifically, we propose to adopt FHIR Draft Standard for Trial Use (DSTU) 2 (hereafter referred to as ''FHIR Release 2'') as a baseline standard conformance requirement. In so doing, we can work with industry to support a conformance testing infrastructure for a full suite of proposals focused on one FHIR release (its associated implementation specifications) and complementary

security and app registration protocols, compared to numerous versions.[81]

The 2015 Edition final rule did not include specific standards or implementation specifications to describe the way in which APIs needed to be designed to meet § 170.315(g)(8). Instead, we specified a functional certification criterion and encouraged the industry to coalesce around a standardized specification for its API functionality, such as the FHIR standard. We did, however, require health IT developers to make their technical API documentation publicly available and we subsequently made such information accessible via the CHPL.

Upon reviewing health IT developers certified to § 170.315(g)(8), approximately 32% have published via the CHPL that they are using FHIR, specifically FHIR Release 2, as of mid-September 2018. Additionally, nearly 51% of health IT developers appear to be using a version of FHIR and OAuth 2.0 together. We also note that when viewed from the perspective of how many providers are served by these FHIR implementers, we estimate that approximate 87% of hospitals and 57% of clinicians are served by developers with a FHIR Release 2 API and 87% of hospitals and 69% of clinicians are served by developers with a FHIR API of any version. In the years since the 2015 Edition final rule, industry stakeholders have made rapid progress to advance the FHIR standard. This includes substantial investments in industry pilots, specification development led through the Argonaut Project[82] production deployment of APIs conformant to FHIR Release 2 following the Argonaut specifications, and the support for FHIR Release 2 in Apple's iOS 11.3, which includes a new ''health records'' app for the iPhone based on these specifications.[83] Therefore, the industry is well prepared and ready to adopt the FHIR standard.

Thus, we propose to adopt FHIR Release 2 as the baseline standard in a new API standards section of our rules at 45 CFR 170.215(a)(1). Additionally, as discussed in further detail below, we reference FHIR Release 2 for use in the new API certification criterion proposed for adoption in § 170.315(g)(10).

Although FHIR Release 3 is published and some health IT developers have included varied support for it in their product(s) at this time, there is limited evidence that its production deployment is as widespread as FHIR Release 2. Thus, we believe that FHIR Release 2 is the most appropriate version to propose to adopt as part of proposed § 170.315(g)(10)'s conformance requirements. This approach would provide a stable and consistent direction in which the industry can go when it comes to deploying (g)(10)–certified APIs that support data access to the USCDI. FHIR Release 2 best reflects the industry's current maturity and implementation readiness, it has been more rigorously tested, and it is largely implemented in most 2015 Edition health IT systems that have and are being deployed in production. Thus, the incremental burden for many health IT developers to get certified to the proposed criterion in § 170.315(g)(10) would be largely limited to the added security and registration conformance requirements we have proposed to include. We recognize, however, that some health IT developers certified to § 170.315(g)(8) chose not to use FHIR and will have more substantial changes to make in order to meet this proposal.

Additionally, FHIR Release 4 has now been published[84] and updated associated implementation specifications are expected to follow. FHIR Release 4 has several key improvements, including certain foundational aspects in the standard and ''FHIR resources'' designated as ''normative'' for the first time. This will lead to acycle of more mature US FHIR Core profiles aligned with Release 4 and additional implementation guidance that explicitly specifies how to handle populations of patient data (batch exports) via FHIR to more efficiently enable population and learning health system-oriented services. Likewise, from an industry update trajectory, we believe that FHIR Release 4's normative resources will be compelling from a maturity and stability perspective such that many health IT developers will either rapidly progress to FHIR Release 4 from Release 3 or skip wide-scale production deployment of FHIR Release 3 altogether, making FHIR Release 4 the next de facto version the industry would move toward and coalesce behind.

Given FHIR Release 4's public release and that the industry will begin to implement Release 4 in parallel with this rulemaking, we request comment on the following options we could pursue for a final rule.

Option 1 (proposed in regulation text): Adopt just FHIR Release 2 for reference in proposed § 170.315(g)(10). This option would require health IT developers seeking certification to build, test, and certify systems solely to FHIR Release 2 and its associated implementation specifications. Under this option, if the National Coordinator approved the use of FHIR Release 3 or 4 (pursuant to the Standards Version Advancement Process) it would occur, at the earliest, one year after a final rule was issued. Given that timing, and the compliance deadlines proposed later in this section, it would mean that health IT developers would have no option but to develop to FHIR Release 2 in order to meet the proposed compliance deadlines.

Option 2: Adopt FHIR Release 2 and FHIR Release 3 in order to introduce optionality into how health IT developers are able to demonstrate compliance with proposed § 170.315(g)(10). In other words, by adopting and referencing both FHIR Release 2 and 3 in proposed § 170.315(g)(10) it would permit a health IT developer to use either one to meet the criterion (*i.e.,* both versions would not be required to be supported and demonstrating only one would be needed to meet certification). Similarly, under this option, if the National Coordinator approved the use of FHIR Release 4 (pursuant to the Standards Version Advancement Process) it would occur, at the earliest, one year after a final rule was issued. Given that timing, and the compliance deadlines proposed later in this section, it would mean that health IT developers would have no option but to develop to FHIR Release 2 or Release 3 in order to meet the proposed compliance deadlines.

Option 3: Adopt FHIR Release 2 and FHIR Release 4 in order to introduce flexibility into how health IT developers are able to demonstrate compliance with proposed § 170.315(g)(10). The full implementation of this option would depend on all applicable corresponding FHIR Release 2 implementation specifications also being published in their FHIR Release 4 formats and available prior to the issuance of a final rule. Provided these FHIR Release 4 implementation specifications are published in time for a final rule, this option would appear to be the best near- and long-term option for the industry. We anticipate this being the case because it would let lagging health IT developers catch up to the FHIR Release 2 baseline while at the same time enable leading health IT developers to move directly and immediately to FHIR Release 4 as a means to meet proposed

[81] In October 2018, ONC released a first version of a FHIR testing tool visit here for more details: *https://inferno.healthit.gov/.*

[82] *http://argonautwiki.hl7.org/index.php?title=Main_Page.*

[83] *https://www.apple.com/newsroom/2018/01/apple-announces-effortless-solution-bringing-health-records-to-iPhone/.*

[84] *http://blog.hl7.org/hl7-publishes-fhir-release-4.*

§ 170.315(g)(10)'s compliance timelines. In other words, unlike Options 1 and 2, the Standards Version Advancement Process would not be necessary and the trajectory of leading health IT developers would be well supported by the certification criterion. We also request comment on a variant of Option 3 that would include a pre-defined cut-over for the permitted use of and certification to FHIR Release 2. We note that if this variant were implemented as part of Option 3, we would likely also need to add a maintenance of certification requirement in the final rule to establish an upgrade timeline to FHIR Release 4 for those health IT developers who originally sought certification for FHIR Release 2. Such a maintenance requirement would seem necessary in order to bring the industry into closer alignment with respect to a more up-to-date national baseline for FHIR.

Option 4: Adopt solely FHIR Release 4 in the final rule for reference in proposed § 170.315(g)(10). This option would require health IT developers seeking certification to build, test, and certify systems solely to FHIR Release 4 and its associated implementation specifications. Again, provided all applicable FHIR Release 4 implementation specifications are published in time for a final rule, this option would appear to be a close preference to Option 3 for industry. We believe this would be the case because by the time a final rule associated with these proposals is issued, it is likely that health IT developers would have close to or over a year's worth of development experience with FHIR Release 4. As a result, many may be poised to introduce their first round of generally available FHIR Release 4 products into production. If ONC were to offer certification to FHIR Release 2 (as in Option 3) this flexibility could unintentionally delay the industry's transition to FHIR Release 4 and slow progress associated with FHIR-based interoperability. The following compliance timeline example attempts to make this point clearer. If, for example, the final rule was effective January 2020, based on other proposals associated with the API Conditions of Certification, health IT developers would have up to 2 years to rollout their (g)(10)–certified API technology, which would mean January 2022. At that point, FHIR Release 4 would have been published for nearly 3 years and FHIR Release 2 would have been published for nearly 6 years. Without a pre-defined cut-over for FHIR Release 2 in Option 3, that certification approach would permit FHIR Release 2 APIs to be deployed in 2022 and used for an indeterminate period of time.

In preparing your comments, please fully review our proposed certification criterion in § 170.315(g)(10) and the accompanying Conditions of Certification attributed to the API-oriented certification criteria. Notably, if we were to adopt another FHIR Release in a final rule as an alternative to FHIR Release 2 for the proposed API criterion in § 170.315(g)(10), then we would also adopt the applicable implementation specifications and FHIR profiles (the US FHIR Core profiles) associated with the FHIR Release in order to support USCDI data access. We highly encourage stakeholders to express their perspective and explicitly note their preferred option in comments.

ii. Proposed Adoption of Associated FHIR Release 2 Implementation Specifications

Our proposal to adopt the FHIR standard alone, however, is insufficient to provide the level of consistent implementation that will be necessary to realize the ''without special effort'' provision in this Condition of Certification. FHIR, much like other standards that are initially developed to be internationally applicable, requires additional implementation specifications in order to further constrain implementation choices and reflect US-based standards policies (such as the use of RxNorm for representing medications). In FHIR, the additional constraints placed on ''base FHIR resources'' are expressed through what are called ''FHIR profiles.'' FHIR Profiles typically provide additional rules about which resource elements must be used and what additional elements have been added that are not part of the base FHIR resource. This can include, but not be limited to, rules about which API features are used and how as well as rules about which terminologies are used in particular elements. The term ''profile'' is a general term that is used in the FHIR standard to describe either an individual FHIR resource, or an entire implementation specification consisting of multiple FHIR resources. Accordingly, we propose to adopt three implementation specifications that will establish a standardized baseline and further constrain API conformance to help assure that APIs can be used ''without special effort.''

We propose to adopt in § 170.215(a)(2) an implementation specification that would list a set of base FHIR resources that Health IT Modules certified to the proposed criterion in § 170.315(g)(10) would need to support. We refer to this proposed initial set of FHIR resources as the ''API Resource Collection in Health'' or ''the ARCH.'' The ARCH would align with and be directed by the data policy specified in the proposed US Core Data for Interoperability (USCDI) standard (discussed in section IV.B.1 of this proposed rule).

As a result, we propose to include 15 FHIR resources in the ARCH's first version. Based on prior industry efforts, including the Argonaut Project to map FHIR resources to the previously defined Common Clinical Data Set (CCDS), we know that the following 13 FHIR resources map to and support the equivalent data classes specified in the USCDI: AllergyIntolerance; CarePlan; Condition; Device; DiagnosticReport; Goal; Immunization; Medication; MedicationOrder; MedicationStatement; Observation; Patient; and Procedure. We also propose to include, specifically for the Patient resource that the ''Patient.address'' and ''Patient.telecom'' elements must be supported as part of the Patient resource. These elements are neither required in the base FHIR resource or additional implementation specifications; however, they are necessary to align with the USCDI's data requirements. With respect to the Device resource, we propose to require that the ''Device.udi'' element follow the human readable representation of the unique device identifier (UDI) found in the recommendation, guidance, and conformance requirements section of the ''HL7 Version 3 Cross Paradigm Implementation Guide: Medical Devices and Unique Device Identification (UDI) Pattern, Release 1,'' a document hosted by HL7.[85] Developers would be held responsible only for the recommendation, guidance, and conformance requirements for HL7 FHIR in the implementation guide and would not be held responsible for other requirements in the implementation guide specific to other standards, including requirements for HL7 Version 2 and HL7 Version 3. For clarity, these proposed requirements are part of the ARCH Version 1 standard.

In addition to these 13 FHIR resources, we have included two additional FHIR resources:

(1) The Provenance resource; and (2) the DocumentReference resource to accommodate clinical notes. These additions would make for a total of 15 FHIR resources to reflect the direction of the USCDI v1. With respect to clinical notes, we understand from our own

[85] *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=487.*

analysis and technical discussions within HL7 that the FHIR DocumentReference resource is best capable of handling the exchange of clinical notes. Since the CCDS was defined over two years ago, we have most frequently heard from provider stakeholders that access to ''clinical notes'' is key, impactful, and highly desirable data that should be accessible via the C–CDAs they exchange as well as via APIs. While we realize the industry may need to develop additional implementation guidance to support clinical notes via FHIR, we believe that including FHIR resources in ARCH Version 1 directly addresses the steady requests we have received from providers to include a focus on the access, exchange, and use of ''clinical notes'' as part of certification. Thus, we propose to include the FHIR DocumentReference resource in the ARCH to support clinical notes. We also clarify that the clinical note text included in this FHIR resource would need to be represented in its ''raw'' text form. In other words, it would be unacceptable for the note text to be converted to another file or format (*e.g.,* .docx, PDF) when it is provided as part of an API response. With respect to the Provenance resource, we believe its inclusion in the ARCH is paramount to the long-term success and use of FHIR-based APIs. While C–CDA's are often critiqued due to their relative ''length,'' the C–CDA often represents the output of a clinical event and includes relevant context. The same will not always be true in an API-context. This is due to the fact that FHIR-based APIs make it significantly easier for apps to request specific data (*e.g.,* just a patient's active medications). Thus, it is equally important over the long-term that the industry not lose sight of the metadata (*i.e.,* the who, what, when, where, why, and how) behind the data that was created. As a result, we believe that this early stage of FHIR deployment is the best time for the industry to build in support for the Provenance resource. Otherwise, if we were to expand the ARCH in future years to include this FHIR resource, we estimate that the developer burden and overall industry impact would be greater than building this support in ''from the start.'' Specifically, and to remain consistent with the USCDI, we propose to require that the ''Provenance.recorded'' (for the author's time stamp) and ''Provenance.agent.actor'' (for the author and author's organization) elements be supported as part of the Provenance resource.

Over time, and as the USCDI is expanded, we also expect to update this implementation specification to expand the ARCH beyond these 15 FHIR resources. Equally, consistent with the Maintenance of Certification requirements described in section VII.B.5 of this proposed rule (the Standards Version Advancement Process proposals), which would permit health IT developers to voluntarily implement and use a new version of an adopted standard or implementation specification so long as certain conditions are met including that the new version is approved by the National Coordinator for use in certification through the Standards Version Advancement Process, health IT developers would be able to update their certified health IT to include (g)(10)-certified API access to a broader set of data once a new version of the ARCH is approved.

The next implementation specification for the FHIR standard we propose to adopt in § 170.215(a)(3) is the Argonaut Data Query Implementation Guide version 1 (Argonaut IG), hosted by HL7.[86] This implementation guide has been pilot tested and is now being implemented for production use by health IT developers. Notably, it specifies FHIR profile constraints for 13 of the associated FHIR resources we propose to include in the ARCH Version 1 and these FHIR profiles support the data included in the USCDI (v1).

The next implementation specification for the FHIR standard we propose the Secretary adopt in § 170.215(a)(4) is the specific portion of the Argonaut IG that refers to the ''Argonaut Data Query Implementation Guide Server'' conformance requirements. While it could be implied through our proposed adoption of the Argonaut IG that these conformance requirements would be included, we seek to make this an explicit requirement for the API certification criterion proposed in § 170.315(g)(10). Conformance to this implementation specification is essential in order to ensure that all FHIR servers are consistently configured to support the defined data queries and ''supported searches'' associated with each Argonaut profiled FHIR resource. For clarity, conformance testing would focus on and be limited to the ''SHALL'' requirements. We also note that the Argonaut Data Query Implementation Guide Server includes conformance requirements for the ''DocumentReference Profile,'' which defines ''how a provider or patient can retrieve a patient's existing clinical document.'' This particular specification was produced in support of the 2015 Edition certification criterion adopted in § 170.315(g)(9). As a result, we clarify that this specific portion of the Server IG and conformance requirement would be out of scope for the purposes of proposed § 170.315(g)(10).

We have separately proposed the FHIR standard and each of these implementation specifications so that the National Coordinator may evaluate industry progress and make a unique or combined determination as to the appropriate time to approve for voluntary upgrade pursuant to the standards version advancement process discussed in more detail in section VII.B.5 as well as subsequently go through rulemaking to adopt a new version of: The FHIR standard, the ARCH, implementation specifications that ''profile'' the resources in the ARCH, and implementation specifications for FHIR server conformance capabilities. While the proposed implementation specifications relate to one another, they can also be updated independently of each other as time goes on. For instance, the National Coordinator could approve a new version of the FHIR standard ''Release 5'' in the future in accordance with the standards version advancement process. In so doing, the National Coordinator could leave the scope of the ARCH the same and update (necessarily) the implementation specifications for the FHIR profiles and FHIR server conformance requirements accordingly to align with the new FHIR version. As an alternative example, the National Coordinator could leave the FHIR standard version the same and approve a new version of the ARCH to include more FHIR resources.

We note that other federal agencies may be adopting the FHIR standard and additional FHIR implementation guides for their program requirements. We plan to coordinate with such other agencies to focus on strategic alignment among the FHIR standard versions, applicable implementation guides, and use cases.

iii. Proposed Adoption of Standards and Implementation Specifications To Support Persistent User Authentication and App Authorization

To enable and support persistent user authentication and app authorization processes, we propose to adopt a standards and additional implementation specification for the FHIR standard. First, we propose to adopt the ''OpenID Connect Core 1.0

[86] *http://www.fhir.org/guides/argonaut/r2/.*

incorporating errata set 1'' standard in § 170.215(b) as it complements the SMART Application Launch Framework Implementation Guide Release 1.0.0 [87] (SMART Guide). The OpenID standard is typically paired with OAuth 2.0 implementations and focuses on user authentication. Second, we propose to adopt the SMART Guide in § 170.215(a)(5) as an additional implementation specification associated with the FHIR standard. This guide is referenced by the Argonaut IG and is generally being implemented by the health IT community as a security layer with which FHIR deployment is being combined (from both a FHIR server and FHIR application perspective). Further, while the SMART Guide includes certain mandatory requirements, we believe three specific aspects are necessary to specifically require in order for certification to enable consistent industry-wide implementation.

The SMART Guide specifies the use of ''refresh tokens'' as optional. We believe that this requirement is necessary in order to enable persistent access by apps, especially in a patient access context. Thus, we propose to make their use mandatory with a minimum refresh token life of 3 months. While this technique would need to be supported for both types of API-enabled services we propose be supported through § 170.315(g)(10), we wish to emphasize that implementing refresh token support is directly intended to enable a patient's ''persistent access'' to their electronic health information without special effort (*i.e.,* without having to frequently re-authenticate and re-authorize while using their preferred app). This proposal aligns with the industry developed security best practice guidelines for OAuth 2.0 implementations, which require support for a short-lived ''access token'' and a long-lived ''refresh token'' that could be subsequently used by the app to obtain a new ''access token'' after the original ''access token'' expires. We believe this approach enhances the seamlessness of a patient's data access and reduces the ''friction'' they would otherwise experience having to re-authenticate and re-authorize. At the same time, because the access token is short lived, this minimizes the risk of a patient's information being accessed by unauthorized users if for some reason the access token is compromised. The technical capabilities that we intend to explicitly test are referenced as part of the proposed API certification criterion in § 170.315(g)(10).

We also propose to require that the ''Standalone Launch'' and ''EHR Launch'' requirements specified in the SMART Guide be supported. We believe that requiring API Technology Suppliers to demonstrate both of these capacities will help ensure greater standardization and ease of use among (g)(10)-certified APIs. When a third-party ''app'' first connects to a FHIR server, it often requires some contextual data to make the app more ''user friendly.'' This information could include things such as the most recent patient encounter or hospital visit. The contextual information depends on how the ''app'' is launched.

When an app is launched from ''outside of an EHR,'' such as from a patient's smartphone or web browser, then the app is considered to be launched in a ''Standalone'' mode. In this mode, the app has to request that the FHIR server provide appropriate contextual information, which can then be used to customize the app's display for the patient. The SMART Guide has standardized the information that such apps can request from FHIR servers and defined it as ''Standalone Launch.''

In other contexts, apps can be launched from ''within the EHR.'' This is typically the case when a third-party app is integrated as part of an EHR technology. In this case, the app is considered to have been launched in the ''EHR'' mode. Typically, when such an app is launched from within an EHR, the user (*e.g.,* provider, nurse) has a patient's record ''open'' or ''active'' in the EHR and expects the app to directly open the same patient when it is launched. In order for this to happen, the app has to request that the FHIR server provides information about the patient record that is currently ''open'' in the EHR. The SMART Guide has standardized this interaction and defined it as ''EHR Launch.''

iv. Proposed Adoption of a New API Certification Criterion in § 170.315(g)(10)

Proposal Overview

To implement the Cures Act, we propose to adopt a new criterion in § 170.315(g)(10) to replace the certification criterion adopted in § 170.315(g)(8). Currently, the criterion adopted in § 170.315(g)(8) focuses on a Health IT Module's ability to provide API functionality that can respond with data for each of the data categories specified in the Common Clinical Data Set. Moreover, its focus on read-access/response to requests for specific types of data most directly aligns with the API uses envisioned by industry stakeholders and the Cures Act, which is why we believe it is necessary and appropriate to replace § 170.315(g)(8). In contrast, we do not propose that it is necessary to replace the certification criteria adopted in § 170.315(g)(7) and (g)(9) because the former does not prescribe specific technical approaches (and can continue to be met as technology evolves) and the latter supports a discrete use case relative to an API function that responds with a C–CDA.

We propose our approach to adopt a replacement for § 170.315(g)(8) that will provide clear regulatory compliance requirements for stakeholders because: (1) 2015 Edition testing and certification to § 170.315(g)(8) will continue throughout this rulemaking; (2) presuming we adopt this (or a modified version of this) proposal in a final rule, it will be easier for the industry to distinguish compliance requirements between two separate certification criteria compared to a time/context-sensitive ''version'' of § 170.315(g)(8); and (3) § 170.315(g)(8) is currently specified in the Base EHR definition so its replacement has compliance effects on health care providers participating in every program that requires the use of Certified EHR Technology, which references the Base EHR definition.

At a high-level, we propose that this new API certification criterion would require FHIR servers to support two types of API-enabled services:

- Services for which a single patient's [88] data is at focus; and
- services for which multiple patients' data are at focus, which, hereafter, we refer to as ''population-level'' to convey the grouped and cohort scope on which the data associated with these services would be focused (*e.g.,* a specific provider's patient panel, all of the patients covered by a particular health plan, a group of patients cared for through an alternative payment model).

This proposed certification criterion would only require mandatory support for ''read'' access for both identified services, though we envision a future version of this certification criterion that could include specific ''write'' conformance requirements (for example, to aid decision support) once FHIR-based APIs are widely adopted. In all cases, this proposed criterion will require that the two types of API services have appropriate security controls implemented. These controls

[87] *https://build.fhir.org/ig/HL7/smart-app-launch/.*

[88] We recognize that individuals may not always be in an active role as a ''patient'' when they use an application to access their data. However, we believe it is clearer for the purposes of readability and policy intent to use the term ''patient'' as opposed to ''individual.''

would ensure a user fully authenticates to the API-enabled data source to which the request is being made and that the user's software application is appropriately authorized to request specified data.

API services that focus on a single patient would include, but not be limited to, those that interact with software applications controlled and used by a patient to access their data as well as software applications implemented by a provider to enhance their own ''internal'' clinical care tools and workflow (*e.g.,* a specialized calculation app). Most, if not all, of these types of interactions are typically orchestrated in a synchronous, real to near-real-time mode via APIs.

Conversely, API services that focus on multiple patients would include, but not be limited to, software applications used by a health care provider to manage various internal patient populations as well as external services a health care provider may contract for to support quality improvement, population health management, and cost accountability vis-à-vis the provider's partners (*e.g.,* health plans). Historically, access to this kind of computing has often been cumbersome, opaque, and required one-off scripting and significant engineering labor with no overarching standardized methods. By shifting this paradigm to a FHIR-based API, we anticipate that the market will be able to respond with a new slate of innovative solutions.

Across this spectrum of population-level uses, the scope or quantity of the data may range from a small group to many hundreds or thousands of patients. Moreover, when ''external'' applications and services are provided access to patient data by the provider, we expect that such access and associated privacy and security protocols would be established consistent with existing legal requirements under the HIPAA Privacy and Security Rules (including business associate agreements), other data use agreements (as applicable), and any other state or federal applicable law. Principally, for the purposes of the proposed certification criterion, we seek to include and ensure through testing and certification that a set of baseline API functionality exists and is deployed for providers to use at their discretion to support their own clinical priorities as well as to use to engage with their partners, such as software developers and developers of third-party applications.

We have explicitly proposed to include support for API services that are population-level focused in this certification criterion because the current certification criterion in § 170.315(g)(8) has largely been tested, certified, and deployed to support the ''patient data request'' use case. In comparison, population-level focused API services are envisioned to support FHIR-based apps that not only improve clinical workflow and decision support but also help advance a learning health system. In so doing, providers, payers, and other stakeholders will be able to make incrementally better use of FHIR's RESTful API and JSON payload to apply modern computing techniques, including big data analyses and machine learning, to account for, assess, and inform the quality and effectiveness of care delivered. As noted in the proposed API standards section, FHIR Release 4 includes technical specifications to enable standardized population-level services via FHIR-based APIs in a more efficient manner than currently possible. If ''Option 3'' or ''Option 4'' is preferred by industry in terms of the FHIR standards options for this certification criterion, these approaches would be demonstrable. Alternatively, if the National Coordinator were to approve FHIR Release 4 for use under this proposed certification criterion (following the Standards Version Advancement Process described in Section VII.B.5 of this preamble) then it would be able to be used to meet these technical expectations.

Lastly, as we considered the necessary oversight responsibilities the Cures Act adds to the Program, we have determined that it would be essential to include a specific population-level API conformance requirement as part of this criterion so that such capabilities could be evaluated post-certification for compliance with (among other requirements) this API Condition of Certification and the information blocking and real world testing Conditions of Certification.

Specific Proposals

In general, we have approached framing § 170.315(g)(10) in the same way we framed § 170.315(g)(8). This new proposed criterion, however, includes some important differences and specificity compared to § 170.315(g)(8). Taken together, the following proposals are designed to establish a consistent set of API implementation requirements aimed at the API Condition of Certification's ''without special effort'' requirement. We propose that API technology presented by a health IT developer (otherwise considered an API Technology Supplier in this context) for testing and certification to the proposed certification criterion in § 170.315(g)(10) would need to meet the requirements outlined below. We seek comment on all of the following proposals.

Data Response

We propose in § 170.315(g)(10)(i) that the health IT presented for testing and certification must be capable of responding to requests for data on a single patient and multiple patients associated with each of the FHIR resources specified in ARCH Version 1 and consistent with FHIR Release 2 and the Argonaut IG implementation specification. More specifically, we clarify that all data elements indicated as ''mandatory'' and ''must support'' by the proposed standards and implementation specifications must be supported and would be in scope for testing. Through this approach, certification will provide for a consistent and predictable starting scope of data from which apps and other services can be developed.

Search Support

We propose to require in § 170.315(g)(10)(ii) that the health IT presented for testing and certification must be capable of responding to all of the ''supported searches'' specified in the Argonaut Data Query Implementation Guide Server, which as a reminder we have proposed for adoption as an implementation specification in § 170.215(a)(4).[89] Given that there is not yet a consistent, standardized specification for FHIR servers to handle searches for multiple patients, we clarify that a health IT developer would be permitted to approach searches for multiple patients in the manner it deems most efficient to meet this proposed certification criterion. We note, consistent with the implementation specifications current scope, that conformance would focus on search associated with a single patient's data. However, we reiterate the health IT presented for testing and certification and as implemented must support searches for multiple patients independent of a required standard for such searches.

For the DocumentReference and Provenance resources, which are currently present in the base FHIR standard, we request comments on the minimum ''search'' parameters that would need to be supported.

[89] *http://www.fhir.org/guides/argonaut/r2/Conformance-server.html.*

App Registration

We propose in § 170.315(g)(10)(iii) that health IT presented for testing and certification must be capable of enabling apps to register with an ''authorization server.'' This proposed conformance requirement would require an API Technology Supplier to demonstrate its registration process, but would not require that it be done according to a specific standard. We considered proposing the OAuth 2.0 Dynamic Client Registration Protocol (*RFC 7591*) standard (''Dynamic Registration'') as the only way to support registration for this certification criterion and request public comment on whether we should require its support as part of a final rule's certification criterion. For clarity, we note that while we have not explicitly required Dynamic Registration as the only way to demonstrate conformance with this specific portion of the certification criterion, API Technology Suppliers would still be allowed to use Dynamic Registration if they so choose.

While requiring Dynamic Registration could create a more consistent registration experience for health IT developers, we did not expressly include this standard because of its relatively low adoption and implementation in the health IT ecosystem. Notably, while the SMART Guide covers a majority of technical steps necessary for an app to connect a FHIR server, it is neutral on the registration process API Technology Suppliers could take. Much like we did with § 170.315(g)(8) in the initial 2015 Edition final rule by not requiring FHIR, we believe that a prudent approach for registration is to require that it be addressed from a functional perspective while the industry reaches consensus on the best techniques to enable registration.

Note, that while this portion of proposed § 170.315(g)(10) focuses on the technical standards conformance, we have also included a specific ''maintenance requirement'' associated with the API Condition of Certification around the timeliness of this registration process in production settings as applicable to API Technology Suppliers. This proposed requirement will ensure that patients are able to use their apps in a timely manner.

We do not intend to test registration capabilities for apps that would be executed within an API Data Provider's clinical environment. We believe this discretion is warranted as API Technology Suppliers and API Data Providers are best poised to innovate and execute various methods for app registration within a clinical environment. However, we request comment on this perspective.

Secure Connection, Authentication and Authorization

We propose in § 170.315(g)(10)(iv) that the health IT presented for testing and certification must be capable of establishing a secure and trusted connection with an application that requests patient data in accordance with the SMART Guide. In the context of this proposed criterion, this would require that an ''authorization server'' be deployed and support, at a minimum, ''authorize'' and ''token'' endpoints and the publication of the endpoint URLs via FHIR server's metadata as specified in the SMART Guide to enable automated discovery by apps. Again, we note, consistent with this implementation specification's current scope, that initial conformance would focus on the secure connection parameters with a single patient's data in mind. Given that there is not yet a consistent, standardized specification for FHIR servers to handle secure connection parameters for multiple patients, we clarify that a health IT developer would be permitted to approach secure connections for multiple patients in the manner it deems most efficient to meet this proposed certification criterion.

When an application connects to request data for the first time, we propose in § 170.315(g)(10)(v)(A) that health IT presented for testing and certification must be capable of demonstrating support for user authentication according to the OpenID Connect Core 1.0 incorporating errata set 1 [90] standard. It should be noted that the OpenID Connect Standard is agnostic to the actual authentication mechanism used by the health IT while providing a standard way for health IT to exchange the authentication information to the app. The primary benefit being that it lets apps verify the identity of the end-user based on the authentication performed by the Authorization Server without having the apps to take additional responsibility for authenticating the user. We also propose in § 170.315(g)(10)(v)(B) that health IT presented for testing and certification must demonstrate that users can authorize applications (in the appropriate context) to access data in accordance with the SMART Guide. Pursuant to this proposed implementation specification described above, we also intend to test health IT in the ''Standalone Launch'' and ''EHR Launch'' modes. Additionally, we clarify that for the purposes of testing and certification, we propose to require that health IT support only a limited set of capabilities related to the OpenID Connect Standard—specifically, only those that are specified in the SMART Guide.

Further, in order to enable patients and providers to get persistent access to health information without having to re-authenticate and re-authorize, we propose to require that a ''refresh token'' must be provided with an expiration period of at least 3 months from the date issued. The ''refresh token'' could be subsequently used by the app to obtain a new ''access token'' after the expiration of the original ''access token.'' Note the proposed refresh token requirement is different than providing an ''access token'' with an extended life, which is typically discouraged from a security best practice perspective so as to prevent unauthorized access if for some reason the access token were to be acquired for use by an unauthorized application.

We propose in § 170.315(g)(10)(vi) that health IT presented for testing and certification must demonstrate that it can support subsequent connections by an app and requests data without requiring the user to re-authorize and re-authenticate when a valid refresh token is supplied. Further, we propose that once a valid refresh token has been used to get a new access token that the FHIR server must demonstrate that it can issue a new refresh token to the app, which must be for a new period no shorter than three months. For example, if an application were issued a refresh token that was good for three months upon its first-ever connection and then subsequently connected to the FHIR server one month later, the FHIR server would need to enable that connection to occur without re-authentication and re-authorization, and it would need to issue a new refresh token for a new three-month period from that access date. Again, we intend to test health IT in the ''Standalone Launch'' and ''EHR Launch'' contexts pursuant to the SMART Guide.

We have proposed this renewal requirement because industry stakeholders at various meetings and conferences at which we have attended have indicated that a constant need for patients to re-authenticate and re-authorize their apps creates usability challenges and may otherwise contradict the Cures Act's intent associated with the phrase ''without special effort.'' Further, we are not aware of a standard, consistent

[90] *http://openid.net/specs/openid-connect-core-1_0.html.*

methodology for specifying the lifetime of refresh tokens in published technical specifications. As a result, we believe our approach would improve the current user experience for patients and providers alike. Additionally, authorization servers maintain binding between the refresh token and the application to whom it was issued, and hence can protect against misuse by unauthorized applications.

We believe that the three-month period is a reasonable length given the proposal for the re-issuance of a new refresh token. However, we acknowledge that this same policy outcome we discuss above could be achieved by, for example, having a two-month period. Accordingly, we seek comment on whether there are available specifications we should review as well as whether there should be a reasonable upper bound from a timing perspective (*e.g.,* one year) after which the user should be required to re-authenticate and re-authorize.

For both the first time connection and subsequent connection proposals, we recognize that there is not yet a consistent, standardized specification for FHIR servers to handle data requests for multiple patients. As noted above, we expect that FHIR Release 4 will have such specificity. However, for the purposes of meeting this proposed certification criterion, we clarify that a health IT developer would be permitted to approach requests for multiple patients in the manner it deems most efficient.

Transparency Through the Publication of API Documentation

In the 2015 Edition final rule we included transparent documentation requirements for all three of the API-focused certification criteria adopted in § 170.315(g)(7) through (g)(9). These requirements specified that documentation associated with API syntax (and other technical descriptors), the software components and configurations that would be necessary in order for a deployed API to successfully work, and the terms of use for the API be made publicly available. We continue to believe that such a requirement is important for proposed § 170.315(g)(10), especially in light of the Cures Act's ''without special effort'' provision. Such transparency and openness is commonplace in many other industries and has fueled innovation, growth, and competition. Further, we believe that full transparency is necessary to ensure that software developers building to a health IT developer's (g)(10)-certified API have a thorough understanding of any requirements against which their software will need to be designed.

In reconciling the 2015 Edition final rule's API documentation requirements with the new expectations set forth by the Cures Act regarding a health IT developer's practices, we have determined that revisions are necessary. Accordingly, we propose to revise the documentation provision in the API certification criteria adopted in § 170.315(g)(7) through (g)(9) as well as reflect the same revision in proposed § 170.315(g)(10) and (11). Specifically, we propose to focus the documentation requirement set forth by the certification criteria on solely the technical documentation associated with the API technology. As a result, we propose to remove the provision in § 170.315(g)(7) through (g)(9) associated with ''terms of use'' as this type of documentation could be considered more reflective of business practice and better placed with other similar requirements. Consistent with the Cures Act's API Condition of Certification, we have proposed more detailed Condition of Certification requirements associated with a health IT developer's API terms of use in order to address business practices that could interfere with and create special effort on the part of an API User.

With respect to the technical documentation that would need to be made publicly available, we recognize that our proposed formal adoption of the FHIR standard and the associated implementation specifications (for § 170.315(g)(10)) would be consistent across all health IT presented for certification. As a result there may be minimal additional documentation needed for these capabilities beyond what is already documented in these standards and specifications. However, pursuant to the limited mandatory scope proposed for ''data response'' (for § 170.315(g)(10)), we believe that API Technology Suppliers should disclose any additional data their (g)(10)-certified API supports in the context of FHIR resources referenced in ARCH Version1 and associated implementation specifications. For example, the Argonaut IG ''Patient Profile'' includes optional elements for marital status, photo, and contact (as in contact person like a guardian or friend). To the degree that a (g)(10)-certified API supports such optional data an API Technology Supplier would be required to convey this support in its published technical documentation. Additionally, we note that other specifications, like the RFC 7591, provide developers some latitude in terms of the information that could be supplied for the purposes of registration.

Thus, we propose in § 170.315(g)(10)(vii) that an API Technology Supplier would need to provide detailed information for all aspects of its (g)(10)-certified API, especially for any unique technical requirements and configurations, such as how the FHIR server handles requests for multiple patients (until such time as there is an approved standardized approach that can be cited) as well as app registration requirements. For aspects that are not unique and are fully specified by the FHIR standard and associated implementation specifications, the developer could include hyperlinks to this information as part of its overall documentation. Further, we propose to include the word ''complete'' in the documentation provision in order to make this point explicit and link this obligation to the associated transparency conditions proposed as part of the overall Condition of Certification. We note for health IT developers that the documentation published must be of the sort and to the level of specificity, precision, and detail that the health IT developer customarily provides to its own employees, contractors, and/or partners who develop software applications for production environments.

Lastly, we note that all of the documentation referenced by this criterion must be accessible to the public via a hyperlink without additional access requirements, including, without limitation, any form of registration, account creation, ''click-through'' agreements, or requirement to provide contact details or other information prior to accessing the documentation. It would also require that such documentation needs to be submitted as part of testing for this certification criterion and subsequently to ONC–ACBs for review prior to issuing a certification.

d. Condition of Certification Requirements

To implement the Cures Act, we have designed this API Condition of Certification in a manner that will complement the technical capabilities described in our other proposals, while addressing the broader technology and business landscape in which these API capabilities will be deployed and used.

Consistent with the attributes we have identified for the statutory phrase ''without special effort,'' our overarching vision for this Condition of Certification is to ensure that (g)(10)-certified APIs, among all API

technology, are deployed in a manner that supports an experience that is as seamless and frictionless as possible. To that end, we seek to promote a standards-based ecosystem that is transparent, scalable, and open to robust competition and innovation.

The specific requirements of this Condition of Certification are discussed in several sections below. These requirements would address certain implementation, maintenance, and business practices for which clear and consistent parameters are needed to ensure that API technology is deployed in a manner that achieves the policy goals we have described. The proposed requirements would also align this Condition of Certification with other requirements and policies of the Cures Act that promote interoperability and deter information blocking, as discussed in more detail in the sections that follow.

i. Scope and Compliance

To start this Condition of Certification, we propose in § 170.404 to apply this Condition of Certification to health IT developers with health IT certified to any of the API-focused certification criteria. These criteria include the proposed ''standardized API for patient and population services'' (§ 170.315(g)(10)) and ''consent management for APIs'' (§ 170.315(g)(11)) as well as the current ''application access—patient selection'' (§ 170.315(g)(7)), ''application access—data category request'' (§ 170.315(g)(8)), ''application access—all data request'' (§ 170.315(g)(9)). In other words, this entire Condition of Certification would not apply to health IT developers that do not have technology certified to any of these API-focused certification criteria. Similarly, this condition is solely applicable to these API-focused certification criteria. As a result, the proposed policies for this Condition of Certification would not apply to a health IT developer's practices associated with, for example, the immunization reporting certification criterion adopted in § 170.315(f)(1) because that criterion is not one of the API-focused criteria. However, health IT developers should remain mindful that other proposals in this proposed rule, especially those related to information blocking, could still apply to its practices associated with non-API-focused certification criteria.

Given the proposed applicability of this condition to current API-focused criteria and that health IT developers with products certified to §§ 170.315(g)(7)–(9) would need to meet new compliance requirements associated with such criteria, we also propose certain compliance timelines associated with this Condition of Certification that would need to be met.

ii. Cures Act Condition and Interpretation of Access to ''All Data Elements''

First, we propose to adopt the Cures Act's API Condition of Certification in § 170.404(a)(1) to fully incorporate the statute's compliance requirements. Second, strictly for the scope of the API Condition of Certification, we propose to interpret the meaning of the phrase ''all data elements of a patient's electronic health record'' as follows.

For the reasons discussed above, the proposed § 170.315(g)(10) certification criterion and associated standards and implementation specifications would facilitate API access to a limited set of data elements (*i.e.,* from the FHIR resources that ARCH Version 1). Accordingly, for the purposes of meeting this portion of the Cures Act's API Condition of Certification, we interpret the scope of: The ARCH; its associated implementation specifications; and the policy expressed around the data elements that must be supported by (g)(10)-certified APIs (*i.e.,* FHIR servers) to constitute ''all data elements.'' Given other proposals related to permitting the use of updated versions of adopted standards and implementation specifications, we expect that (g)(10)-certified APIs will be able to support access to more data over time in response to updates to the USCDI and the ARCH. As these updates occur, the industry would be able to incrementally approach the totality of data that can be electronically accessed, exchanged, and used pursuant to the Cures Act's reference to ''all data elements.''

Again, we reiterate that this specific interpretation does not extend beyond the API Condition of Certification and cannot be inferred to reduce the scope or applicability of other Cures Act Conditions of Certification or the information blocking proposals, which necessarily will include a larger scope of data. For example, other Conditions of Certification will apply to health IT developer behaviors associated with data that are not part of the USCDI or ARCH, such as the proposals at 45 CFR 170.402 and the proposals in Part 171, which apply across several stakeholders including health information networks and health care providers.

iii. Transparency Conditions

We propose as part of this Condition of Certification that API Technology Suppliers be required to make specific business and technical documentation freely and publicly accessible. Thus, we propose to adopt several transparency conditions as part of § 170.404(a)(2).

Similar to our policy associated with the API-focused certification criteria, we propose in § 170.404(a)(2)(i) that all published documentation be complete and available via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps. For example, the API Technology Supplier cannot impose any access requirements, including, without limitation, any form of registration, account creation, ''click-through'' agreements, or requirement to provide contact details or other information prior to accessing the documentation.

Terms and Conditions Transparency

In addition to technical documentation, we propose in § 170.404(a)(2)(ii)(A) to require API Technology Suppliers to publish all terms and conditions for use of its API technology. We believe that it is important to make this information readily accessible to API Data Providers, API Users, app developers, and other persons. This transparency would ensure that these stakeholders do not experience ''special effort'' in the form of unnecessary costs or delays to obtain the terms and conditions for API technology. Further, we believe that full transparency is necessary to ensure that app developers have a thorough understanding in advance of any terms or conditions that might apply to them and do not encounter unanticipated hurdles once they have committed to developing software or attempt to implement or deploy such software in production.

We note that this requirement would apply to *all* terms and conditions that apply to the API technology and its use. As noted above, and for the purposes of this proposal's scope, ''API technology'' refers to the specified API capabilities for Health IT Modules certified to § 170.315(g)(7) through (11) under the Program. We consider ''terms and conditions'' to include any fees, restrictions, limitations, obligations, registration process requirements, and other terms or conditions that would be material and needed to:

- Develop software applications to interact with the API technology;
- distribute, deploy, and enable the use of software applications in production environments that use the API technology;
- use software applications, including to access, exchange, and use EHI by means of the API technology;

• use any EHI obtained by means of the API technology; and

• register software applications (as discussed in more below).

In addition, we propose in § 170.404(a)(2)(ii)(B) that any and all permitted fees charged by an API Technology Supplier for the use of its API technology must be published and described in detailed, plain language as part of its publicly available terms and conditions. The description of the fees must include all material information, including, but not limited to, the persons or classes of persons to whom the fee applies; the circumstances in which the fee applies; and the amount of the fee, which for variable fees must include the specific variable(s) and methodology(ies) that will be used to calculate the fee.

For the purposes of the specific transparency conditions proposed in § 170.404(a)(2) and their relationship and applicability to API Technology Suppliers with products already certified to § 170.315(g)(7), (8), or (9), we propose to establish a compliance date of six months from the final rule's effective date (which would give developers approximately eight months from the final rule's publication date) to revise their existing API documentation to come into compliance with the final rule. We also recognize that API Technology Suppliers will need to update the proposed publicly available information from time to time. Thus, for the purposes of and with respect to subsequent updates to this information, we expect API technology suppliers to make clear to the public the timing information applicable to their disclosures (*e.g.,* effective/as of date or last updated date) in order to prevent out of sync discrepancies in what an API Technology Supplier's public documentation states and what it may be communicating directly to its customers (*e.g.,* a change in fees is directly communicated to customers but not reflected at the publicly available hyperlink pursuant to its responsibilities under this proposal). If an API Technology Supplier's actions are out of sync with its publicly provided documentation, the API Technology Supplier would be at risk of violating this Condition of Certification. We request public comment on whether this expectation should be formally specified in regulation text or if these ''effective date'' approaches for changes to transparency documentation are common place such that it would be a standard practice as part of making this documentation available.

We also note that API Technology Suppliers would be expected to revise and/or construct terms and conditions for its API technology that account for and reflect the proposals associated with this API Condition of Certification and information blocking policies. In so far as an API Technology Supplier would find it necessary to enforce its published terms and conditions, we caution API Technology Suppliers to be mindful of whether such terms and conditions would be acceptable and consistent with the aforementioned policies in the first place—as an impermissible term or condition would be problematic regardless of whether it was actively enforced.

We propose in § 170.404(a)(2)(ii)(C) a final transparency condition associated with API Technology Suppliers' application developer verification processes that takes into account the fact that we did not propose to adopt the Dynamic Registration standard as part of proposed § 170.315(g)(10). Had we proposed requiring Dynamic Registration, we would have also proposed a specific Condition of Certification that would have outright prohibited API Technology Suppliers from identity proofing or verifying authenticity of an app developer when it came to apps that were designed to enable patient access.

On balance, however, we believe that permitting API Technology Suppliers to institute a process to verify the authenticity of application developers will foster additional trust in the growing API ecosystem. We seek comments and recommendations on factors that would enable registration with minimal barriers. For example, permitting API Technology Suppliers to do one- time verification of the app developers (or even rely on centralized vetting by a trusted third party), which would allow the developer's future apps to automatically register without case-by- case checks (or checks for each API Technology Supplier with which the app developer interacts). One risk to consider with Dynamic Registration plus a prohibition on vetting, for instance, is that it would be much easier for a malicious app developer to spoof another legitimate app developer's app. Such an action could ultimately lead to confusion and distrust in the market. However, the Dynamic Registration option would minimize barriers to registration especially for third-party apps designed to enable patient access. We seek comments on options and trade-offs we should consider.

Accordingly, and weighing those concerns with the Cures Act's ''without special effort'' provision and our proposed information blocking policies, we specifically propose to permit API Technology Suppliers to institute a process to verify the authenticity of application developers so long as such process is completed within five business days [91] of receipt of an application developer's request to register their software application with the API technology's authorization server. To clarify, this verification process would need to focus specifically on the application developer—not its software application(s). We also clarify that API Technology Suppliers would have the discretion to establish their verification process so long as the process is objective and the same for all application developers and it can reasonably be completed within the five business days—otherwise such a process could risk implicating/violating other elements of this proposed API Condition of Certification as well as information blocking behaviors. The following includes a few non-exhaustive examples of verification techniques that could be used by an API Technology Supplier to have additional certainty about the application developer with whom they are interacting: Instituting a ''penny verification'' process, requiring some form of corporate documentation, or requesting other forms of authenticating documentation or transactions.

We believe that five business days is sufficient time for API Technology Suppliers to weed out malicious developers seeking to deceive the API Technology Supplier, API Data Providers or API Users, but request public comment on other timing considerations. Moreover, we clarify that this proposed Condition of Certification is meant to set the upper bound for a verification process an API Technology Supplier would be permitted to take and should not be interpreted as compelling API Technology Suppliers to institute such a process (*i.e.,* API Technology Suppliers would not be required to institute a verification process). Rather, for those API Technology Suppliers that see it in their (as well as their customers and patients) best interests to institute such a process, we have laid out the rules that we believe meet the Cures Act's without special effort expectations. If an API Technology Supplier chooses not to institute an app developer verification process prior to enabling the production use of an app, it would solely need to meet the Maintenance of Certification

[91] We consider a ''business day'' to include the normal work days and hours of operation during a week (Monday through Friday), excluding federal holidays and weekends.

requirement associated with enabling apps for production use discussed in more detail below.

We remind stakeholders that even in the case where an API Technology Supplier chooses not to vet app developers, the apps would *not* have carte blanche access to a health care provider's data. To the contrary, such apps will still be registered and thus be identifiable and able to have their access deactivated by an API Technology Supplier or health care provider (API Data Provider) if they behave in anomalous or malicious ways (*e.g.,* denial of service attack). And a patient seeking access to their data using the app will need to authenticate themselves (using previously issued credentials by a health care provider or trusted source) and authorize: (1) The app to connect to the FHIR server; and (2) specify the scope of the data the app may access.

As a separate matter, we also recognize that in order to assure health care providers that the apps they use within their health IT will operate appropriately, will fully integrate into workflow, and will not degrade overall system performance, that API Technology Suppliers may establish additional mechanisms to vet app developers. Such mechanisms could fit into the ''value-added services'' permitted fee and result in the app being acknowledged or listed by the health IT developer in some special manner (*e.g.,* in an ''app store,'' ''verified app'' list). While our proposals do not specify any explicit limits to the nature and governance of these approaches, we wish to caution health IT developers that even though such processes have a reasoned basis in providing an added layer of trust above and beyond the basic production-readiness of an app, they can equally be used as a means to prevent, limit, and otherwise frustrate innovation, competition, and access to the market. Such an outcome would be inconsistent with the Cures Act, could directly violate the specific Condition of Certification associated with fees permitted for value-added services, and could constitute information blocking.

iv. Permitted Fees Conditions

General Proposals Involving Fees

As part of this API Condition of Certification, we propose to adopt specific conditions that would set boundaries for the fees API Technology Suppliers would be permitted to charge and to whom those permitted fees could be charged. As a reminder, these proposals would only apply to a health IT developer's business practices associated with its ''API technology'' (*i.e.,* the capabilities certified to § 170.315(g)(7) through (11)). We seek comment on all of the following proposals.

In § 170.404(a)(3)(i)(A), we propose to establish a general prohibition on API Technology Suppliers imposing fees associated with API technology. This general prohibition is meant to ensure that API Technology Suppliers do not engage in pricing practices that create barriers to entry and competition for apps and API-based services that health care providers seek to use. These outcomes would be inconsistent with the goal of enabling API-based access, exchange, and use of EHI by patients and other stakeholders without special effort.

In establishing this general prohibition, we have been mindful of the need for API Technology Suppliers to recover their costs and to earn a reasonable return on their investments in providing API technology that has been certified under the Program. Accordingly, we have identified categories of ''permitted fees'' that API Technology Suppliers would be permitted to charge and still be compliant with the Condition of Certification and Program requirements, and discuss these proposals below. We emphasize, however, and propose in detail below, that API Technology Suppliers would not be permitted in any way whatsoever to impose fees on any person in connection with an API Technology Supplier's work to support the use of API technology to facilitate a patient's ability to access, exchange, or use their EHI.

We note that other than for fees charged for ''value-added services'' (proposed in § 170.404(a)(3)(iv)), the fees permitted under this Condition of Certification must arise between an API Technology Supplier and an API Data Provider. Any fee that arises in connection with an API User's use of API technology would need to exist solely between the API Data Provider and the API User. This policy reinforces the autonomy that we believe API Data Providers should have to establish relationships with API Users. However, as discussed in detail below, API Technology Suppliers would be permitted to charge API Data Providers based on the usage activities of API Users.

We also seek to clarify that while the proposed permitted fees set the boundaries for the fees API Technology Suppliers would be permitted to charge and to whom those permitted fees could be charged, they do not prohibit who may pay the API Technology Supplier's permitted fee. In other words, these conditions limit the party from which an API Technology Supplier may require payment, but they do not speak to who may pay the fee. For example, if through some type of relationship/agreement an API User or other party offered to pay the fee an API Data Provider owed to an API Technology Supplier, that practice would be allowed and unaffected under these conditions. This is an acceptable practice because the fee is first arrived at between the API Technology Supplier and API Data Provider, and then API Technology Supplier receives payment from another party via the API Data Provider or directly on behalf of the API Data Provider. As a general matter, we note that stakeholders should be mindful of other federal and state laws and regulations that could prohibit or limit certain types of relationships involving remuneration.

We note that the proposed ''permitted fees conditions'' align with the requirements of the information blocking exceptions proposed in 45 CFR 171.204 and 171.206. Any fee that would not be covered by those exceptions, and that would, therefore, be suspect under the information blocking provision, would equally not be permitted by this API Condition of Certification. We strongly encourage readers to review our proposals associated with those exceptions, which are contained in sections VIII.D.4 and VIII.D.6 of this preamble, respectively.

Permitted Fees—General Conditions

We propose in § 170.404(a)(3)(i)(B) general conditions that an API Technology Supplier's fee must satisfy in order for such fee to be expressly permitted and thus not contravene the proposed Condition of Certification. First, we propose in § 170.404(a)(3)(i)(B)*(1)* that in order to be a permitted fee, a fee imposed by an API Technology Supplier must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. This would require an API Technology Supplier to apply fee criteria that, among other things, would lead an API Technology Supplier to come to the same conclusion with respect to the permitted fee's amount each time it interacted with a class of persons or responded to a request. Accordingly, the fee could not be based on the API Technology Supplier's subjective judgment or discretion.

Moreover, in order to be permitted, the fee must not be based in any part on

whether the API User is a competitor or potential competitor, or on whether the API Data Provider or API User will be using the data accessed via the API technology in a way that facilitates competition with the API Technology Supplier. This condition is intended to ensure that any fee charged by an API Technology Supplier does not have the purpose or effect of excluding or creating impediments for competitors, business rivals, or other persons engaged in developing or enabling the use of API technology. We believe these fee limitations are necessary in light of the potential for API Technology Suppliers to use their control over API technology to engage in discriminatory practices that create barriers to API technology. These principles are consistent with the approach described in section VIII of this preamble (''information blocking'').

Second, we propose in § 170.404(a)(3)(i)(B)*(2)* that in order to be a permitted fee, a fee imposed by an API Technology Supplier must be reasonably related to the API Technology Supplier's costs of supplying and, if applicable, supporting the API technology to, or at the request of, the API Data Provider to whom the fee is charged. For example, the API Technology Supplier would not be permitted to charge a fee when the underlying costs relevant to the supply or service have already been accounted for or recovered through other fees (regardless of whether such fees were charged to the API Data Provider or to other persons). Moreover, an API Technology Supplier that conditioned access to its API technology on revenue-sharing or the entry into a royalty agreement would be at significant risk of imposing a fee that bore no plausible relation to the costs incurred by the API Technology Supplier to develop the API technology or support its use by API Users.

Third, we propose in § 170.404(a)(3)(i)(B)*(3)* to require that in order to be a permitted fee, the costs of supplying, and if applicable, supporting the API technology upon which the fee is based must be reasonably allocated among all customers to whom the API technology is supplied or for whom it is supported. A reasonable allocation of costs would require that the API Technology Supplier allocate its costs in accordance with criteria that are reasonable and between only those API Data Providers that either cause the costs to be incurred or benefit from the associated supply or support of the API technology. If an API Technology Supplier developed API technology that could be supplied to multiple customers with minimal tailoring, the core costs of developing its API technology should be allocated among those customers when recovered as a fee. The API Technology Supplier would not be permitted to recover the total of its core costs from each customer. Similarly, when an API Technology Supplier uses shared facilities and resources to support the usage of API technology, it would need to ensure that those shared costs were reasonably allocated between all of the customers that benefited from them. However, whenever an API Technology Supplier is required to provide services and incur costs that are unique to a particular customer, it would not need to distribute those costs among other customers that had deployed its API technology.

Last, we propose in § 170.404(a)(3)(i)(B)*(4)* to require that in order to be a permitted fee, the API Technology Supplier must ensure that fees are not be based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the API technology in a way that facilitates competition with the API Technology Supplier. The use of such criteria would be suspect because it suggests the fee the API Technology Supplier is charging is not based on its reasonable costs to provide the API technology or services and may have the purpose or effect of excluding or creating impediments for competitors, business rivals, or other persons engaged in developing or enabling the use of API technologies and services.

We request comments on these general conditions for permitted fees and whether commenters believe we have created effective guardrails to ensure that fees do not prevent EHI from being accessed, exchanged, and used through the use of APIs without special effort.

Specific Proposed Permitted Fees

As noted above, we propose that API Technology Suppliers would be prohibited from charging fees associated with API technology unless such fees are expressly permitted. Additionally, as a reminder, the scope of ''API technology'' subject to these proposals would only include certified health IT that fulfill the API-focused certification criteria adopted or proposed for adoption at 45 CFR 170.315(g)(7) through (g)(11). Thus, all other API functionality provided by a health IT developer with its product(s) that have no link to these certified capabilities would not be subject to this Condition of Certification.

The following proposals outline the specific circumstances in which an API Technology Supplier would be permitted to charge fees associated with API technology certified under the Program. A fee that satisfies one of the permitted fees in §§ 170.404(a)(3)(ii)–(iv) must also satisfy each of the general conditions in § 170.404(a)(3)(i) in order to be permitted and for its recovery compliant with this Condition of Certification.

Permitted Fee for Developing, Deploying, and Upgrading API Technology

In § 170.404(a)(3)(ii), we propose to permit an API Technology Supplier to charge API Data Providers reasonable fees for developing, deploying, and upgrading API technology. Fees for ''developing'' API technology comprise the API Technology Supplier's costs of designing, developing, and testing API technology to specifications that fulfill the requirements of the API-focused certification criteria adopted or proposed for adoption at 45 CFR 170.315(g)(7) through (g)(11). Fees for developing API technology must not include the API Technology Supplier's costs of updating the non-API related capabilities of the API Technology Supplier's existing health IT, including its databases, as part of its development of the API technology. These costs would be connected to past business decisions made by the API Technology Supplier and typically arise due to health IT being designed or implemented in nonstandard ways that unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using EHI. The recovery of the costs associated with updating an API Technology Supplier's health IT generally would be inconsistent with the Cures Act requirement that API technology be deployed ''without special effort.''

The API Technology Supplier's fees for ''deploying'' API technology comprise the API Technology Supplier's costs of operationalizing API technology in a production environment. Such fees include, but are not limited to, standing up hosting infrastructure, software installation and configuration, and the creation and maintenance of API Data Provider administrative functions. An API Technology Supplier's fees for ''deploying'' API technology does not include the costs associated with managing the traffic of API calls that access the API technology, which an API Technology Supplier can only recover under the permitted fee for usage support costs under § 170.404(a)(3)(iii). For clarity, we reiterate that for the purpose of this Condition of Certification, we consider

that API technology is ''deployed'' by the customer—the API Data Provider—that purchased or licensed it.

The API Technology Supplier's fees for ''upgrading'' API technology comprise the API Technology Supplier's costs of supplying an API Data Provider with an updated version of API technology. Such costs would include the costs required to bring API technology into conformity with new requirements of the Program, upgrades to implement general software updates (not otherwise covered by development fees or under warranty), or developing and releasing newer versions of the API technology at the request of an API Data Provider.

The nature of the costs that can be charged under this category of permitted fees will depend on the scope of the work to be undertaken by an API Technology Supplier (*i.e.,* how much or how little labor an API Data Provider requires of the API Technology Supplier to deploy and upgrade the API technology being supplied). For example, where an API Data Provider decides to fully outsource the deployment of its API technology to its API Technology Supplier, the API Technology Supplier's costs will include the work associated with the development of the API technology, the work deploying the API technology, and any work upgrading the API technology.

We propose that any fees that an API Technology Supplier charges for developing, deploying, or upgrading API technology must be charged solely to the API Data Provider(s) for whom the capabilities are deployed. We propose this limitation because we believe that these costs should be negotiated between the API Technology Supplier that supplies the capabilities and the API Data Provider (*i.e.,* health care provider) that implements them in its production environment. In our view, it is inappropriate to pass these costs on to API Users as doing so would impose considerable costs on the API Data Provider's current or potential partners, such as those offering third-party applications and services, as well as the end-users of API technology and would amount to the kind of ''special effort'' that the Cures Act's API Condition of Certification seeks to prevent.

Subject to the general conditions proposed in § 170.404(a)(3)(i) and discussed above, API Technology Suppliers can recover the full range of reasonable costs associated with developing, deploying, and upgrading API technology over time. We believe it is important that API Technology Suppliers be able to recover these costs and earn a reasonable return on their investments so that they have adequate incentives to make continued investments in these technologies. In particular, we anticipate that API Technology Suppliers will need to continually expand the data elements and upgrade the capabilities associated with Certified APIs as the FHIR standard and its implementation specifications mature, and the National Coordinator expands the USCDI and ARCH.

Permitted Fee To Recover Costs of Supporting API Usage for Purposes Other Than Patient Access, Exchange, and Use

In § 170.404(a)(3)(iii) we propose to permit an API Technology Supplier to charge usage-based fees to API Data Providers to the extent that the API technology is used for purposes other than facilitating access, exchange, or use of EHI by patients or their applications, technologies, or services.

We consider ''usage-based'' fees to be the fees imposed by an API Technology Supplier to recover the costs that would typically be incurred supporting API interactions at increasing volumes and scale within established service levels. That is, ''usage-based'' fees recover costs incurred by an API Technology Supplier due to the actual use of the API technology once it has been deployed (*e.g.,* costs to support a higher volume of traffic, data, or number of apps via the API technology). We acknowledge that API Technology Suppliers could adopt a range of pricing methodologies when charging for the support of API usage. We expect that API usage support fees would only come into play when the API Technology Supplier acts on behalf of the API Data Provider to deploy its API technology. Thus, the costs recovered under ''usage-based'' fees would only be able to reflect ''post-deployment'' costs. As such, ''usage-based'' fees would not be allowed to include any costs necessary to prepare and ''get the API technology up, running, and ready for use,'' which are costs that we propose should be recovered as part of the deployment services delivered by the API Technology Supplier if permitted under § 170.404(a)(3)(ii). We believe this Condition of Certification offers the flexibility necessary to accommodate reasonable pricing methodologies and will allow API Technology Suppliers to explore innovative approaches to recovering the costs associated with supporting API use as a permitted fee.

As discussed above, we expect that API usage support fees would only come into play when the API Technology Supplier acts on behalf of the API Data Provider to deploy its API technology. Conversely, in scenarios where the API Data Provider, such as a large hospital system, assumes full responsibility for the technical infrastructure necessary to deploy and host the API technology it has acquired, the volume and scale of its usage would be the API Data Provider's sole responsibility. As a result, in this scenario and under our proposal's structure, an API Technology Supplier would not be permitted to charge usage-based fees. Instead, the API Technology Supplier would be limited to the fees it would be permitted to recover through the ''development, deployment, upgrade'' permitted fee discussed above.

We reiterate, that ''usage-based'' fees would need to be settled between an API Technology Supplier and API Data Provider. The API Technology Supplier would have no standing to go around or through the API Data Provider to issue fees to, for example, a population health analytics company engaged by an API Data Provider who accesses the API Data Provider's data via the API technology.

We propose that any usage-based fees associated with API technology be limited to the recovery of the API Technology Supplier's ''incremental costs.'' An API Technology Supplier's ''incremental costs'' comprise the API Technology Supplier's costs that are directly attributable to supporting API interactions at increasing volumes and scale within established service levels. We propose than an API Technology Supplier should ''price'' its costs of supporting access to the API technology by reference to the additional costs that the API Technology Supplier would incur in supporting certain volumes of API use. In practice, we expect that this means that API Technology Suppliers will offer a certain number of ''free'' API calls based on the fact that, up to a certain threshold, the API Technology Supplier will not incur any material costs in supporting API technology in addition to the costs recovered for deployment services. However, after this threshold is exceeded, we expect that the API Technology Supplier will impose usage-based costs commensurate to the additional costs that the API Technology Supplier must incur to support API technology use at increasing volumes and scale.

We expect that API Technology Suppliers would charge fees that are correlated to the incremental ratchetting up of the cost required to meet increased demand. For example, if, at a certain volume of API calls, the API Technology Supplier needed to deploy

additional server capacity, the associated incremental cost of bringing an additional server online could be passed on to the API Data Provider because the API technology deployed on behalf of the API Data Provider was the subject of the higher usage. Up until the point that the threshold is reached, the additional server capacity was not required and so the API Technology Supplier would not be permitted to recover the cost associated with it. Moreover, the additional server capacity would support ongoing demand up to a certain additional volume, and so the API Technology Supplier would not be permitted to recover the costs of further additional server capacity until the then current capacity was exhausted.

Notwithstanding the above, we note that API Technology Suppliers may choose to charge for their API usage support services on a ''pay as you go'' basis, such as a fee-per-call pricing structure. This approach could be consistent with the requirement that the API Technology Supplier only impose its incremental costs, and the requirements of this Condition of Certification more generally. However, depending on the amount being charged, this pricing model is open to abuse, with API Data Providers at risk of paying unreasonably high fees if the volume of API use is high and when the API Data Provider does not share in the benefits enjoyed by the API Technology Supplier when delivering a service at scale. As such, the API Technology Supplier would need to be careful to ensure that the total fees paid by an API Data Provider were reasonably related to the API Technology Supplier's costs of supporting the API technology. Where the fees paid over a reasonable measuring period were not reasonably related to the API Technology Supplier's costs, they would not be permitted.

We are also aware that API Technology Suppliers may offer a pricing structure for API usage support based on unlimited API calls. That is, the API Technology Supplier may charge a flat-fee irrespective of the volume of traffic accessing the API technology. Such a pricing model would be allowed under the proposed condition provided that the API Technology Supplier's fee for API usage support was reasonably related to the cost of the services that it had agreed to provide. This would mean that the API Technology Supplier would need to make a realistic estimate of the volume of API calls that it would need to support to fulfill any service level promised, and calculate its fee based on the costs of supporting that call volume. So long as the API Technology Supplier made a realistic estimate of the anticipated volume and support level, the legitimacy of the API Technology Supplier's fees, and its ability to recover them as permitted fees, would be unaffected by API Users making lower than expected use of API technology.

In the context of this proposed permitted fee's scope and the proposed general prohibition on fees, we seek to make clear that API Technology Suppliers would be prohibited from charging (or including in their contracts and agreements with API Data Providers) any usage-based fees for API uses that are associated with the access, exchange, and use of EHI by patients or their applications, technologies, or services. This would include, among other things, API calls or other transactions initiated by or on behalf of a patient, including third parties (*e.g.,* an application or any other technology or service) authorized by the patient or their representative to request data on their behalf.

Usage fees associated with the access, exchange, and use of EHI by patients is a specific example of a prohibited fee that would fit under the general prohibition of a ''fee not otherwise permitted'' and is based on several considerations. First, such fees between an API Technology Supplier and API Data Provider would likely be passed on directly to patients, creating a significant impediment to their ability to access, exchange, and use their EHI, without special effort, through applications and technologies of their choice. More fundamentally, most of the information contained in a patient's electronic record has been documented during the practice of medicine or has otherwise been captured in the course of providing health care services to patients. In our view, patients have effectively paid for this information, either directly or through their employers, health plans, and other entities that negotiate and purchase health care items and services on their behalf. Thus, our proposal reflects our belief that it is inappropriate to charge patients additional costs to access this information, whether those costs are charged directly to patients or passed on as a result of fees charged to persons that provide apps, technologies, and services on a patient's behalf.

To be clear, if an API Data Provider sought to employ API technology for the limited purpose of making EHI available to patients and their apps, the API Data Provider's API Technology Supplier would have no legitimate basis to charge the API Data Provider, or any other person, for the ''patient access'' usage-based costs associated with the API technology.

Any unreasonable fees associated with a patient's access to their EHI may be suspect under the information blocking provision. Such fees may also be inconsistent with an individual's right of access to their PHI under the HIPAA Privacy Rule (45 CFR 164.524).)

In addition to our proposal in § 170.404(a)(3)(iii)(A) and detailed above that this permitted fee would not include any costs incurred by the API Technology Supplier to support uses of the API technology that facilitate a patient's ability to access, exchange, or use their electronic health information, we also propose to explicitly exclude two additional costs from this permitted fee. In § 170.404(a)(3)(iii)(B), we propose that this permitted fee would not include costs associated with intangible assets (including depreciation or loss of value), except the actual development or acquisition costs of such assets. For instance, an API Technology Supplier could not charge an API Data Provider a fee based on the purported ''cost'' of allowing the API Data Provider to use the API Technology Supplier's patented API technology. As discussed in more detail in section VIII.D.4 (Information Blocking), we believe it would be inappropriate to permit an actor to charge a fee based on these considerations, which are inherently subjective and could invite the kinds of rent-seeking and opportunistic pricing practices that create barriers to access, use, and exchange of EHI and impede interoperability.

In § 170.404(a)(3)(iii)(C), we propose that this permitted fee would not include opportunity costs, except for the reasonable forward-looking cost of capital. These speculative costs could include revenues that an API Technology Supplier could have earned had it not provided the API technology. We clarify that the exclusion of opportunity costs would not preclude an API Technology Supplier from recovering its reasonable forward-looking cost of capital. We believe these costs are relatively concrete and that permitting their recovery will protect incentives for API Technology Suppliers to invest in developing and providing interoperability elements (as described in section VIII.D.4).

Permitted Fee for Value-Added Services

In § 170.404(a)(3)(iv) we propose to permit an API Technology Supplier to charge fees to API Users [92] for value-

[92] In this context a health care provider, which could otherwise be an ''API Data Provider'' in one context, may equally be an API User in a different

added services supplied in connection with software that can interact with the API technology. These ''value-added services'' would need to be provided in connection with and supplemental to the development, testing, and deployment of software applications that interact with API technology. Critically, fees would not be permitted if they interfere with an API User's ability to efficiently and effectively develop and deploy production-ready software. This means that in order to be permitted, an API User could not be required to incur the fee in order to develop and deploy a production-ready software application that interacts with the API technology acquired by the API Data Provider. Rather, a fee will only be permitted if it relates to a service that a software developer can elect to purchase, but is not required to purchase in order to develop and deploy production-ready apps.

We believe it appropriate to permit this type of fee because API Technology Suppliers may offer a wide-range of market differentiating services to make it attractive for API Users to develop software applications that can interact with the API technology supplied by an API Technology Supplier. Such services could include advanced training, premium development tools and distribution channels, and enhanced compatibility/integration testing assessments. For example, an API Technology Supplier would be permitted to charge fees for value-added services that would be associated with but go beyond the scope set by the (g)(10)–certified API, such as write access, co-branded integration into the API Technology Supplier's product(s) workflow, co-marketing arrangements, and promoted placement in an API Technology Supplier's app store. That said, we caution API Technology Suppliers that value-added services would have to be made available in a manner that complies with other requirements of this Condition of Certification and with the information blocking provision.

To illustrate the scope of the fees permitted under this proposal, we clarify that the permitted value-added services fee would enable an API Technology Supplier to recover certain costs associated with operating an ''app store.'' However, those fees cannot interfere with an API User's ability to efficiently and effectively develop and deploy production-ready apps without special effort. We are aware that API Technology Suppliers offer services associated with the listing and promotion of apps beyond basic app placement. Such fees would be permitted, so long as the API Technology Supplier ensured that basic access and listing in the app store was provided free of charge if an app developer depended on such listing to efficiently and effectively develop and deploy production-ready apps without special effort. Fees charged for additional/specialized technical support or promotion of the API User's app beyond these basic access and listing services would also be permitted. In contrast, if an API Technology Supplier required, for example, a software developer's app to go through a paid listing process as a dependency/precondition to be able to be deployed (and generally accessible) to the API Technology Supplier's health care provider customers to use, this would not be a permitted fee under this Condition of Certification, would constitute special effort, and could raise information blocking concerns.

Prohibited Fees

As discussed above, we proposed that any API-related fee imposed by an API Technology Supplier that is not expressly permitted is prohibited. This approach is necessary because, as discussed in section VIII.C.5.c of this proposed rule, we continue to receive evidence that some health IT developers are engaging in practices that create special effort when it comes to API technology. These practices include fees that create barriers to entry or competition as well as rent-seeking and other opportunistic behaviors. For example, some health IT developers are conditioning access to technical interoperability documentation on revenue-sharing or royalty agreements that bear no plausible relation to the costs incurred by the health IT developer to provide or enable its use. We are also aware of discriminatory pricing policies that have the purpose or effect of excluding competitors from the use of APIs and other interoperability elements. These practices close off the market to innovative applications and services that could empower patients and enable providers to deliver greater value and choice to health care consumers and additional service providers.

To address these concerns we provide the following non-exhaustive examples of fees for services that API Technology Suppliers would be prohibited from charging:

- Any fee for access to the documentation that an API Technology Supplier is required to publish or make available under this Condition of Certification.
- Any fee for access to other types of documentation or information that a software developer may reasonably require to make effective use of API technology for any legally permissible purpose.
- Any fee in connection with any services that would be essential to a developer or other person's ability to develop and commercially distribute production-ready applications that use API technology. These services could include, for example, access to ''test environments'' and other resources that an app developer would need to efficiently design and develop apps. The services could also include access to distribution channels if they are necessary to deploy production-ready software and to production resources, such as the information needed to connect to FHIR servers (endpoints) or the ability to dynamically register with an authorization server.

Permitted Fees Request for Comment

We request comment on any additional specific ''permitted fees'' not addressed above that API Technology Suppliers should be able to recover in order to assure a reasonable return on investment. Furthermore, we request comment on whether it would be prudent to adopt specific, or more granular, cost methodologies for the calculation of the permitted fees. Commenters are encouraged to consider, in particular, whether the approach we have described will be administrable and appropriately balance the need to ensure that patients, providers, app developers, and other stakeholders do not encounter unnecessary costs and other special effort with the need to provide adequate assurance to API Technology Suppliers, investors, and innovators that they will be able to earn a reasonable return on their investments in API technology. We welcome comments on whether the approach adequately balances these concerns or would achieve our stated policy goals, and we welcome comments on potential revisions or alternative approaches. We encourage detailed comments that include, where possible, economic justifications for suggested revisions or alternative approaches.

Record-Keeping Requirements

To provide appropriate accountability, we propose in § 170.404(a)(3)(v) that API Technology Suppliers must keep for inspection

context. Given this potential dual role for health care providers, we have focused on API Users as the party to whom a fee may be charged for the purposes of this permitted fee.

detailed records of all fees charged with respect to API technology and all costs that it claims to have incurred to provide API technology to API Data Providers. To provide assurance that the API Technology Supplier's fees are reasonably related to the API Technology Supplier's costs, the API Technology Supplier would need to document, with the same level of detail, any fees charged and associated costs incurred to provide other services to which any portion of the costs could reasonably be attributed. For example, if the API Technology Supplier charges a fee that reflects its costs for internet servers used to provide the API technology, the API Technology Supplier would need to document the costs of any other internet-based services it provides, as well as any other purposes for which the internet servers are used.

Separately, an API Technology Supplier would need to document the criteria it used to allocate any costs across relevant customers, requestors, or other persons. The criteria must be documented in a level of detail that would enable determination as to whether the API Technology Supplier's cost allocations are objectively reasonable and comply with the cost accountability requirements, including whether fees reflect the API Technology Supplier's actual costs reasonably incurred, were allocated reasonably and between only those API Data Providers that either cause the costs to be incurred or benefit from the associated supply or support of the API technology, and were distributed across customers and other relevant persons in a permissible manner, as described above.

We note that an API Technology Supplier must retain its accounting records consistent with the retention requirement proposed for adoption as part of the Assurances Condition of Certification (proposed for adoption in § 170.402). In the event that a potential violation of this Condition and Maintenance of Certification creates a conformance fact-finding scenario by ONC or information blocking is investigated, we believe that this period of time would provide ONC with appropriate visibility into the API Technology Supplier's business practices.

We request comment on whether these requirements provide adequate traceability and accountability for costs permitted under this API Condition of Certification. We also seek comment on whether to require more detailed accounting records or to prescribe specific accounting standards.

iv. Openness and Pro-Competitive Conditions

We propose that API Technology Suppliers would have to comply with certain requirements to promote an open and competitive marketplace. As a general condition, we propose in § 170.404(a)(4) that API Technology Suppliers must grant API Data Providers (*i.e.,* health care providers who purchase or license API technology) the sole authority and autonomy to permit API Users to interact with the API technology deployed by the API Data Provider. We reinforce this general condition through more specific proposed conditions proposals discussed below that would require API Technology Suppliers to provide equitable access to API technology, which would include granting the rights and providing the cooperation necessary to enable apps to be deployed that use the API technology to access, exchange, and use EHI in production environments.

As important context for these proposals, we note that the API technology required by this Condition of Certification falls squarely within the concept of ''essential interoperability elements'' described in section VIII.C.4.b of this preamble and, as such, are subject to strict protections under the information blocking provision. As a corollary, to the extent that API Technology Suppliers claim an intellectual property right or other proprietary interest in the API technology, they must take care not to impose any fees, require any license terms, or engage in any other practices that could add unnecessary cost, difficulty, or other burden that could impede the effective use of the API technology for the purpose of enabling or facilitating access, exchange, or use of EHI. Moreover, even apart from these information blocking considerations, we believe that, as developers of technology certified under the Program, API Technology Suppliers owe a special responsibility to patients, providers, and other stakeholders to make API technology available in a manner that is truly ''open'' and minimizes any costs or other burdens that could result in special effort. The proposed conditions set forth below are intended to provide clear rules and expectations for API Technology Suppliers so that they can meet these obligations.

Non-Discrimination

We propose in § 170.404(a)(4)(i) that an API Technology Supplier must adhere to a strictly non-discriminatory policy regarding the provision of API technology. As a starting point, we propose to require in § 170.404(a)(4)(i)(A) that API Technology Suppliers comply with all of the requirements discussed in section VIII.C.4.b of this proposed rule regarding the non-discriminatory provision of interoperability elements. Accordingly, and consistent with developers' obligations under the Program and our expectation that API technology be truly ''open,'' we propose to require that API Technology Suppliers must provide API technology to API Data Providers on terms that are no less favorable than they would provide to themselves and their customers, suppliers, partners, and other persons with whom they have a business relationship. This requirement would apply to both price and non-price terms and thus would apply to any fees that the API Technology Supplier is permitted to charge under the ''permitted charges conditions'' of this Condition of Certification. We believe this requirement would ensure that API Data Providers (*i.e.,* health care providers) who purchase or license API technology have sole authority and autonomy to permit third-party software developers to connect to and use the API technology they have acquired.

Next, we propose in § 170.404(a)(4)(i)(B) that any terms and conditions associated with API technology would have to be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. For example, if the API Technology Supplier applied an ''app store'' entry/listing process unequally and added arbitrary criteria based on the use case(s) an app was focused on, such business practices would not comply with this specific condition and could also be in violation of the information blocking provision.

Moreover, we propose in § 170.404(a)(4)(i)(C) that an API Technology Supplier would be prohibited from offering or varying such terms or conditions on the basis of impermissible criteria, such as whether the API User with whom the API Data Provider has a relationship is a competitor, potential competitor, or will be using EHI obtained via the API technology in a way that facilitates competition with the API Technology Supplier. The API Technology Supplier would also be prohibited from taking into consideration the revenue or other value the API User with whom the API Data Provider has a relationship may derive from access, exchange, or use of EHI obtained by means of the API technology. We believe these proposals

will help promote greater equity and competition in market as well as prevent discriminatory business practices by API Technology Suppliers.

Rights To Access and Use API Technology

We propose in § 170.404(a)(4)(ii)(A) that an API Technology Supplier would have to make API technology available in a manner that enables API Data Providers and API Users to develop and deploy apps to access, exchange, and use EHI in production environments. To this end, we propose that an API Technology Supplier must have and, upon request, must grant to API Data Providers and their API Users all rights that may be reasonably necessary to access and use API technology in a production environment. In other words, this proposal is focused on the provision of rights reasonably necessary to access and use API technology and does not extend to other intellectual property maintained by the API Technology Supplier, especially intellectual property that has no nexus with the access and use of API technology. In situations where such a nexus exists, even partially, the API Technology Supplier would have the duty to determine a method to grant the applicable rights reasonably necessary to access and use the API technology. And if practicable, under these partial cases, we note that it would be possible for the API Technology Supplier to exclude the intellectual property that would have no impact on the access and use of the API technology.

Accordingly, following our proposal, API Technology Suppliers would need to grant API Data Providers and their API Users with rights that could include but not be limited to the following in order to sufficiently support the use of the API technology:

- For the purposes of developing products or services that are designed to be interoperable with the API Technology Supplier's health IT or with health IT under the API Technology Supplier's control.
- Any marketing, offering, and distribution of interoperable products and services to potential customers and users that would be needed for the API technology to be used in a production environment. Note, API Technology Suppliers, pursuant to the ''value-added services'' permitted fee, would be able to offer and charge for services such as preferential marketing agreements, co-marketing agreements, and other business arrangements so long as such services are beyond what is necessary for the API technology to be put into use in a production environment.
- Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.

Relatedly, in § 170.404(a)(4)(ii)(B) we propose to prohibit an API Technology Supplier from imposing any collateral terms or agreements that could interfere with or lead to special effort in the use of API technology for any of the above purposes. We note that these collateral terms or agreements may also implicate the information blocking provision for the reasons described in section VIII.D.3.c of this preamble. These specific proposed conditions would expressly prohibit an API Technology Supplier from conditioning any of the rights described above on the requirement that the recipient of the rights do, or agree to do, any of the following:

- Pay a fee to license the rights described above, including but not limited to a license fee, royalty, or revenue-sharing arrangement.
- Not compete with the API Technology Supplier in any product, service, or market.
- Deal exclusively with the API Technology Supplier in any product, service, or market.
- Obtain additional licenses, products, or services that are not related to or can be unbundled from the API technology.
- License, grant, assign, or transfer any intellectual property to the API Technology Supplier.
- Meet additional developer or product certification requirements.
- Provide the API Technology Supplier or its technology with reciprocal access to application data.

These prohibitions largely mirror those proposed under the exception to the information blocking definition in § 171.206 and reflect the same concerns expressed in that context in section VIII.D.3.c of this preamble. However, we note the following important distinction: Whereas proposed § 171.206 would permit a developer to charge a reasonable royalty to license interoperability elements, this API Condition of Certification would not permit any such royalty, license fee, or other type of fee of any kind whatsoever pursuant to the general fee prohibition proposed in the ''permitted charges condition.'' This additional limitation reflects the more exacting standards that apply to API Technology Suppliers with respect to the provision of API technology under this Condition of Certification. While we believe that, for the reasons described in section VIII.D.3.c of this preamble, health IT developers should generally be permitted to charge reasonable royalties for the use of their intellectual property, we consider API technology to be a special case. Certified health IT developers (*i.e.,* API Technology Suppliers) are required to provide these capabilities as part of their statutory duty to facilitate the access, exchange, and use of patient health information from EHRs ''without special effort.'' We believe the language requiring that these capabilities be ''open'' precludes an API Technology Supplier from conditioning access to API technology on the payment of a royalty or other fee, however ''reasonable'' the fee might otherwise be.

We clarify that the prohibitions explained above against additional developer or Health IT Module certification requirements and, separately, against requirements for reciprocal access to application data, are within the scope of the collateral terms prohibited by proposed § 171.206 even though these additional API Technology Supplier requirements are not explicitly referenced by that exception because they are not generally applicable to all types of interoperability elements. Nevertheless, permitting an API Technology Supplier to impose these kinds of additional requirements would be inconsistent with the Cures Act's expectation that API technology be made available openly and in a manner that promotes competition. For the same reason such practices may raise information blocking concerns.

API Technology Suppliers—Additional Obligations

To support the use of API technology in production environments, we propose in § 170.404(a)(4)(iii) that an API Technology Supplier must provide all support and other services that are reasonably necessary to enable the effective development, deployment, and use of API technology by API Data Providers and its API Users in production environments. In general, the precise nature of these obligations will depend on the specifics of the API Technology Supplier's technology and the manner in which it is implemented and made available for specific customers. Therefore, with the following exceptions, we do not delineate the API Technology Supplier's specific support obligations and instead propose a general requirement to this effect in § 170.404(a)(4)(iii).

Changes and Updates to API Technology and Terms and Conditions

We propose to require in § 170.404(a)(4)(iii)(A) that API Technology Suppliers must make reasonable efforts to maintain the compatibility of the API technology they develop and assist API Data Providers to deploy in order to avoid disrupting the use of API technology. Similarly, we propose in § 170.404(a)(4)(iii)(B) that prior to making changes or updates to its API technology or to the terms or conditions thereof, an API Technology Supplier would need to provide notice and a reasonable opportunity for its API Data Provider customers and registered application developers to update their applications to preserve compatibility with its API technology or to comply with any revised terms or conditions. Without this opportunity, clinical and patient applications could be rendered inoperable or operate in unexpected ways unbeknownst to the users or software developers.

Further, we note that this proposal aligns with the exception to the information blocking definition proposed in § 171.206. As explained in section VIII.D.3.c of this preamble, the information blocking definition would be implicated were an API Technology Supplier to make changes to its API technology that ''break'' compatibility or otherwise degrade the performance or interoperability of the licensee's products or services that incorporate the licensed API technology. We propose these additional safeguards are important in light of the ease with which an API Technology Supplier could make subtle ''tweaks'' to its technology or related services, which could disrupt the use of the licensee's compatible technologies or services and result in substantial competitive and consumer injury.

We clarify that this requirement would in no way prevent an API Technology Supplier from making improvements to its technology or responding to the needs of its own customers or users. However, the API Technology Supplier would need to demonstrate that whatever actions it took were necessary to accomplish these purposes and that it afforded the licensee a reasonable opportunity under the circumstances to update its technology to maintain interoperability. Relatedly, we recognize that an API Technology Supplier may have to suspend access or make other changes immediately and without prior notice in response to legitimate privacy, security, or patient safety-related exigencies. Such practices would be permitted by this Condition of Certification provided they are tailored and do not unnecessarily interfere with the use of API technology. From an information blocking standpoint, if such practices interfered with access, exchange, or use of EHI, the API Technology Supplier could seek coverage under the exceptions to the information blocking provision described in section VIII.D of this preamble. For instance, if the suspended access was in response to a privacy exigency, the API Technology Supplier may be able to seek coverage under the exception for promoting the privacy of EHI at proposed § 171.202.

e. Maintenance of Certification Requirements

We propose to adopt Maintenance requirements for this Condition of Certification. These maintenance requirements would be duties that we believe the Cures Act expected API Technology Suppliers (*i.e.,* health IT developers) would need to comply with in the course of maintaining their Health IT Module(s)' certification.

i. App Registration Timeliness

In the specific context of application registration, we wish to underscore that to provide a frictionless experience for developers of these applications and individuals that use them, an API Technology Supplier would be required to provide all services and other support necessary to ensure that such apps can be deployed and used in production without any additional assistance or intervention by the API Technology Supplier. For this reason, we propose in § 170.404(b)(1) a specific requirement for API Technology Suppliers that they would need to ''register'' (in connection with the API technology functionality proposed in § 170.315(g)(10)(iii)) and enable all applications for production use within one business day of completing its verification of an application developer's authenticity as described in proposed § 170.404(a)(2)(ii)(C). We propose this explicit requirement is necessary in order to ensure that a patient's ability to use an app of their choice is not artificially or intentionally slowed by an API Technology Supplier, causing special effort on the part of the patient to gain access to their EHI. We also emphasize that this is specific duty for API Technology Suppliers in the course of maintaining the Health IT Module(s)' certificate to which their API technology is associated. In instances where an API Technology Supplier chooses not to perform app developer verification processes described in proposed § 170.404(a)(2)(ii)(C), it would need to solely meet this one business day requirement from the point of having received a request for registration.

ii. Publication of FHIR Endpoints

In order to interact with a FHIR RESTful API, an app needs to know the ''FHIR Service Base URL,'' which is often referred to colloquially as a ''FHIR server's endpoint.'' [93] The public availability and easy accessibility of this information is a central necessity to assuring the use of FHIR-based APIs without special effort, especially for patient access apps. Accordingly, we propose to adopt in § 170.404(b)(2) a specific requirement that an API Technology Supplier must support the publication of Service Base URLs for all of its customers, regardless of those that are centrally managed by the API Technology Supplier or locally deployed, and make such information publicly available (in a computable format) at no charge. In instances where an API Technology Supplier is contracted by an API Data Provider to manage its FHIR server, we expect that this administrative duty will be relatively easy to manage. In instances where an API Data Provider assumes full responsibility to ''locally manage'' its FHIR server, the API Technology Supplier would be required, pursuant to this proposed maintenance requirement, to obtain this information from its customers. We strongly encourage API Technology Suppliers, health care providers, HINs and patient advocacy organizations to coalesce around the development of a public resource or service from which all stakeholders could benefit. We believe this would help scale and enhance the ease with which Service Base URLs could be obtained and used.

iii. Providing (g)(10)–Certified APIs to API Data Providers

We propose in § 170.404(b)(3) that an API Technology Supplier with API technology previously certified to the certification criterion in § 170.315(g)(8) must provide all API Data Providers with such API technology deployed with API technology certified to the certification criterion in § 170.315(g)(10) within 24 months of this final rule's effective date. We believe this Maintenance of Certification requirement will permit ONC to monitor and facilitate the rollout to health care providers of this important functionality. This is of particular relevance as we propose below to include this functionality in the 2015 Base EHR definition in place of the

[93] *http://hl7.org/fhir/http.html#general.*

current ''application access—data category request'' certification criterion (§ 170.315(g)(8)), which means health care providers will need this functionality to meet the Certified EHR Technology (CEHRT) for associated Centers for Medicare & Medicaid Services (CMS) programs.

f. 2015 Edition Base EHR Definition

As described in detail above, we have propose to adopt a new certification criterion in § 170.315(g)(10) that would replace the current criterion adopted in § 170.315(g)(8) and as referenced in the 2015 Edition Base EHR definition expressed in § 170.102. This change is necessary to fully implement the Cures Act and ensure that API Technology Suppliers have the requisite incentive to deploy standardized APIs that can be used ''without special effort'' and API Data Providers have added incentive to adopt such functionality. As result, we propose to create a phase-in for the proposed API certification criterion in § 170.315(g)(10) from the issuance of a subsequent final rule. This phase-in period includes separate and sequential time for API Technology Suppliers and API Data Providers.

Consistent with our proposed compliance timing for the certification criterion proposed for adoption in § 170.315(b)(10), we propose to add compliance timeline language to the 2015 Edition Base EHR definition for the transition from § 170.315(g)(8) to § 170.315(g)(10) that would reflect a total of 24 months from the final rule's effective date (which practically speaking would be 25 months because of the 30-day delayed effective date). We believe this approach is best because it identifies a single, specific date for both API Technology Suppliers and API Data Providers by which upgraded API technology needs to be deployed in production. We also believe that 24 months is sufficient for this upgrade because the scope and nature of our proposals intersect and reflect a large portion of capabilities API Technology Suppliers have already developed and deployed to meet § 170.315(g)(8). Moreover, this single date enables API Technology Suppliers (based on their client base and IT architecture) to determine the most appropriate timeline for development, testing, certification, and product release cycles in comparison to having to meet an arbitrary ''must be certified by this date'' requirement.

5. Real World Testing

The Cures Act requires, as a Condition and Maintenance of Certification under the Program, that health IT developers have successfully tested the real world use of the technology for interoperability in the type of setting in which such technology would be marketed. The Cures Act defines interoperability as ''health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and does not constitute information blocking as also defined by the Cures Act.'' [94] We propose to codify this interoperability definition in § 170.102. We further note that we propose in section VIII of this proposed rule to codify the definition of information blocking included in the Cures Act in § 171.103.

The Program issues, and will continue to issue under our real world testing approach, certifications to health IT through a process whereby health IT is assessed against the testing requirements established by ONC. Often, this means health IT is tested by an ONC–ATL in a laboratory environment through methods that include a testing proctor's visual inspection of functions, review of developer-provided documentation of functions, and testing tools with simulation test data. An ONC–ACB evaluates the results of testing and makes a determination, based on these test results and an assessment of compliance with other Program requirements, to issue the health IT a certificate. Over the course of the Program's existence, ONC has emphasized the continued conformance of certified health IT products post-certification in real world and clinical settings. For example, ONC expanded the responsibilities of ONC–ACBs in the 2015 Edition final rule to require that they perform in-the-field surveillance. We did this to affirm the Program's long-standing expectations that certified health IT continue to operate in accordance with certification requirements when implemented in the field (80 FR 62707–62719). These efforts are also in line with the Cures Act's real world testing Condition of Certification through their focus on system interoperability and exchange of information as deployed and used in care environments—that is to say, in the ''real world.''

The objective of real world testing is to verify the extent to which certified health IT deployed in operational production settings is demonstrating continued compliance to certification criteria and functioning with the intended use cases as part of the overall maintenance of a health IT's certification. Real world testing should ensure certified health IT has the ability to share electronic health information with other systems. Real world testing should assess that the certified health IT is meeting the intended use case(s) of the certification criteria to which it is certified within the workflow, health IT architecture, and care/practice setting in which the health IT is implemented. Accordingly, we propose that successful real world testing means for the purpose of this Condition of Certification that:

- The certified health IT continues to be compliant to the certification criteria to which it is certified, including the required technical standards and vocabulary codes sets;
- The certified health IT is exchanging electronic health information in the care and practice settings for which it is intended for use; and
- Electronic health information is received by and used in the certified health IT.

We propose to limit the applicability of this Condition of Certification to health IT developers with Health IT Modules certified to one or more 2015 Edition certification criteria focused on interoperability and data exchange, which are:

- The care coordination criteria in § 170.315(b);
- The clinical quality measures (CQMs) criteria in § 170.315(c)(1) through (c)(3);
- The ''view, download, and transmit to 3rd party'' criterion in § 170.315(e)(1);
- The public health criteria in § 170.315(f);
- The application programming interface criteria in § 170.315(g)(7) through (g)(11); and
- The transport methods and other protocols criteria in § 170.315(h).

The 2015 Edition certification criteria that are not included in the proposed list include many functionality-based criteria, administrative criteria, and, overall, criteria that do not focus on interoperability *and* exchange of data. In particular, we do not propose to include the 2015 Edition paragraph (a) ''clinical'' certification criteria in this list because they do not focus on interoperability and exchange of data. However, the data in the paragraph (a) criteria largely will be covered through the USCDI as a minimum data set expected for exchange; the USCDI is included in such criteria as ''transitions

[94] Defined in Section 3022 of the Cures Act.

of care'' (§ 170.315(b)(1)), ''view, download, and transmit to 3rd party'' (§ 170.315(e)(1)), and the API criteria (*i.e.,* § 170.315(g)(9) and (10)).

We solicit comment on whether to include the ''patient health information capture'' certification criteria in § 170.315(e)(3), including the value of real world testing these functionalities compared to the benefit for interoperability and exchange. We also solicit comment on whether any other 2015 Edition certification criteria should be included or removed from the applicability list for this Condition of Certification.

To fully implement the real world testing Condition of Certification as described above, we propose Maintenance of Certification requirements that would require health IT developers to submit publicly available prospective annual real world testing plans and retrospective annual real world testing results for its certified health IT that include certification criteria focused on interoperability. As we considered the various approaches to implement this Cures Act requirement on health IT developers, we determined that health IT developers would be best positioned to construct how their certified health IT could be tested in the real world. Moreover, by requiring health IT developers to be responsible for facilitating their certified health IT testing in production settings and being held accountable to publicly publish their results, we would balance the respective burden of this statutory requirement with its intended assurances for health care providers. Additionally, ONC is not adequately resourced to centrally administer a real world testing regime among each health IT developer and its customers, nor do we have the specific relationships with health care providers that health IT developers do. Lastly, even if ONC were positioned to support and scale a real world testing regime, we would run the risk of having one-size-fits-all tools that would not necessarily get to the level of detail and granularity necessary and reflective of different health care settings and different scopes of practice that use certified health IT.

Given these considerations, we propose that a health IT developer must submit an annual real world testing plan to its ONC–ACB via a publicly accessible hyperlink no later than December 15, of each calendar year for each of its certified 2015 Edition Health IT Modules that include certification criteria specified for this Condition of Certification. Prior to submission to the ONC–ACB, the plan would need to be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information. The plan would need to include all health IT certified to the 2015 Edition through August 31 of the preceding year. The plan would also need to address the health IT developer's real world testing for the upcoming calendar year and include, for each of the certification criteria in scope:

- The testing method(s)/methodology(ies) that will be used to demonstrate real world interoperability, including a mandatory focus on scenario- and use case-focused testing;
- The care and practice setting(s) that will be tested for real world interoperability, including conformance to certification criteria requirements, and an explanation for the health IT developer's choice of care setting(s) to test; [95]
- The timeline and plans for voluntary updates to standards and implementation specifications that ONC has approved (further discussed below);
- A schedule of key real world testing milestones;
- A description of the expected outcomes of real world testing;
- At least one measurement/metric associated with the real world testing; and
- A justification for the health IT developer's real world testing approach.

The intended testing methods/methodologies would need to address testing scenarios, use cases, and workflows associated with interoperability. Testing may occur in the operational setting using real patient data, in an environment that mirrors the clinical setting using synthetic or real patient data, or in the clinical setting with synthetic data intermixed. Note that when Health IT developers who are HIPAA business associates are conducting testing using ePHI, such testing must be conducted consistent with their business associate agreements and other compliance responsibilities. The health IT developer may also partner with other health IT developers to perform real world testing. We would expect developers to consider such factors as the size of the organization that production systems support, the type of organization and setting, the number of patient records and users, system components and integrations, and the volume and types of data exchange in planning for real world testing. We would also expect developers to explain how they will incorporate voluntary standards updates in their real world testing as discussed further below. While we are not proposing a minimum proportion of the customer base that must be covered in real world testing, we highly encourage developers to find ways to ensure, to the extent practical, proportionate coverage of their customer base that balances the goals of real world testing with burden to providers. Health IT developers would not be required to test the certified health IT in each and every setting in which it is intended for use as this would likely not be feasible due to the associated burden; however, developers must address their choice of care and/or practice settings to test and ONC encourages developers test in as many settings as feasible. Additionally, health IT developers would be required to provide a justification for their chosen approach. Because our approach provides great flexibility for health IT developers with respect to demonstrating compliance, we believe it is imperative that they provide a justification to explain their methodology. Through the transparent reporting of their real world testing plans, the public will have an opportunity to consider a health IT developer's chosen approach(es) and whether it is sufficiently comprehensive to provide assurance that the certified health IT has satisfactorily demonstrated its satisfaction of Program requirements including interoperability in real world settings relevant to their needs.

Health IT developers should consider existing testing tools and approaches that may be used to assess real world interoperability. For example, we encourage health IT developers to consider metrics of use and exchange from existing networks, communities, and tools including, but not limited to, Surescripts, Carequality, CommonWell Health Alliance, the C–CDA One-Click Scorecard, and DirectTrust. We do not believe that testing through the ONC-approved test procedures is sufficient to demonstrate real world use as the test procedures developed for initial laboratory testing and certification are generally setting agnostic, focused on standards conformance, and do not always test the full scope of the certification criteria's intended functionality. We also clarify that the

[95] We do not propose to specifically define or limit the care settings and leave it to the health IT developer to determine. As an example, health IT developers can consider categories, including but not limited to, those used in the EHR Incentive Programs (*https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/October2017_MedicareEHRIncentivePayments.pdf*); long-term and post-acute care; pediatrics; behavioral health; and small, rural, and underserved settings.

ONC-approved test procedures are not intended for use in in-the-field surveillance or for real world testing. Further, we do not believe connect-a-thons are a valid approach to testing real world use of health IT because they do not necessarily assess interoperability and functionality in live settings, but rather test developer/vendor connectivity in a closed test environment. Health IT developers may consider working with an ONC–ACB to have the ONC–ACB oversee the execution of the health IT developer's real world testing plans, which could include in-the-field surveillance per § 170.556, as an acceptable approach to meet the requirements of the real world testing Condition of Certification.

We propose that health IT developers with multiple certified health IT products that may include the same interoperability-focused certification criteria intended to be implemented in the same settings have the discretion to design their real world testing plans in a way that efficiently tests a combination of products. Likewise, health IT developers may find portions of their real world testing plans are transferrable to their other certified products; thus a health IT developer could choose to submit a real world testing plan that covers multiple certified products as appropriate and as long as there is traceability to the specific certified Health IT Modules. To be clear, developers of health IT products deployed through the cloud who offer their products for multiple types of settings would be required to test the same capability for those different settings. However, we solicit comment on whether we should offer an exemption for services that truly support all of a developer's customers through a single interface/engine and whether this would be sufficient to meet the intent of the real world testing Condition of Certification. Additionally, while the developers' plans must address each of the interoperability-focused certification criteria in their certified health IT, developers can and should design scenario-based test cases that incorporate multiple functionalities as appropriate for the real world workflow and setting.

We propose that a health IT developer would submit annual real world testing results to their ONC–ACBs via a publicly accessible hyperlink no later than January 31, of each calendar year for the preceding calendar year's real world testing. Real world testing results for each interoperability-focused certification criterion must address the elements required in the previous year's testing plan, describe the outcomes of real world testing with any challenges encountered, and provide at least one measurement or metric associated with the real world testing. As noted above, developers are encouraged to use metrics demonstrating real world use from existing networks and communities. We seek comment on whether ONC should require developers submit real world testing results for a minimum ''core'' set of general metrics/measurements and examples of suggested metrics/measurements. We also invite comment on the proposed annual frequency and timing of required real world testing results reporting.

We acknowledge that a subsequent final rule for this proposed rule may not provide sufficient time for health IT developers to develop and submit plans for a full year of real world testing in 2020. If such a situation comes to fruition, we expect to provide an appropriate period of time for developers to submit their plans and potentially treat 2020 as a ''pilot'' year for real world testing. We would expect that such pilot testing conform to our proposed real world testing to the extent practical and feasible (*e.g.,* same criteria but for a shorter duration and without the same consequences for non-compliance). We welcome comments on this potential approach.

We clarify, and propose, that even if a health IT developer does not have customers or has not deployed their certified Health IT Module at the time the real world testing plan is due, the health IT developer would still need to submit a plan that addresses its prospective testing for the coming year for any health IT certified prior to August 31 of the preceding calendar year. If a health IT developer does not have customers or has not deployed their certified Health IT Module when the annual real world testing results are due, we propose that the developer would need to report as such to meet the proposed Maintenance of Certification requirement. For further clarity, a developer would not need to report on any health IT certified after August 31, in the preceding year.

Standards Version Advancement Process

As new and more advanced versions [96] become available for adopted standards and implementation specifications applicable to criteria subject to the real world testing Condition and Maintenance of Certification Requirements, we believe that a health IT developer's ability to conduct ongoing maintenance on its certified Health IT Module(s) to incorporate these new versions is essential to support interoperability in the real world. Updated versions of standards reflect insights gained from real-world implementation and use. They also reflect industry stakeholders' interests to improve the capacity, capability, and clarity of such standards to meet new, innovative business needs, which earlier standards versions cannot support. Therefore, as part of the real world testing Condition of Certification, we propose a Maintenance of Certification flexibility that we refer to as the Standards Version Advancement Process. The Standards Version Advancement Process would permit health IT developers to voluntarily use in their certified Health IT Modules newer versions of adopted standards so long as certain conditions are met, not limited to but notably including successful real world testing of the Health IT Module using the new version(s).

We propose to establish the Standards Version Advancement Processnot only to meet the Cures Act's goals for interoperability, but also in response to the continuous stakeholder feedback that ONC has received through prior rulemakings and engagements, which requested that ONC establish a predictable and timely approach within the Program to keep pace with the industry's standards development efforts. Rulemaking has not kept up with the pace of standards development and deployment in the health care market. There is no better evidence of this reality than by example from our 2015 Edition rulemaking finalized approximately three years ago and before the Cures Act added Conditions and Maintenance of Certification provisions to the PHSA. Two version updates of the National Health Care Survey standard (versions 1.1 and 1.2) have been issued since we adopted version 1.0 in the 2015 Edition final rule (October 16, 2015). Health IT developer and health care provider compliance and use of these versions has and will be necessary for submission to Centers for Disease Control and Prevention (CDC) even though the certification criterion adopted in § 170.315(f)(7) continues to require conformance to version 1.0. Similarly, many other adopted standards have seen multiple newer versions introduced to the market since we issued the 2015 Edition final rule, such as for eCQM reporting or e-prescribing. The proposed Standards

[96] We note that standards development organizations and consensus standards bodies use various nomenclature, such as ''versions,'' to identify updates to standards and implementation specifications.

Version Advancement Process flexibility gives health IT developers the option to avoid such unnecessary costs and can help reduce market confusion by enabling certified Health IT Modules keep pace with standards advancement and market needs including but not limited to those related to emerging public health concerns.

We have also been informed by stakeholders that, in other cases, ONC's inability to more nimbly identify and incorporate newer versions to standards and implementation specifications that were already adopted by the Secretary into the Program has perversely impacted standards developing organization (SDO) processes. Although SDOs can rapidly iterate version updates to standards and implementation specifications to address ambiguities and implementation challenges reported from the field and to particularly address matters that adversely impact interoperability, the lack of a clear path for that work effort to be timely realized as part of the Program's certification requirements has had a chilling effect on the pace of change. It can also affect the willingness of volunteers at these SDOs to devote their time to make updates that would be outdated by the time ONC goes through a rulemaking, which can be years. Stakeholders have indicated that certified health IT developers, customers and users of certified health IT, and the SDO industry have been technologically restricted and innovation-stunted as a result of our prior regulatory approach, which focused on certification assuring compliance only to the version of a standard adopted in regulation and did not provide an avenue for the Program to accommodate iterative updates to standards during the time between rulemakings. With the passage of the ''maintenance of certification'' provision in § 4002 of the Cures Act, we believe the approach proposed here is in line with our new statutory authority regarding Conditions of Certification and Maintenance of Certification and would better and more timely support market demands for widespread interoperability.

In supporting more rapid advancement of interoperability, we believe the proposed Standards Version Advancement Process approach will benefit patient care, improve competition, and spur additional engagement in standards development. To this point, currently, if the USCDI v1 were adopted as currently proposed in § 170.213 and then needed to be updated to add just one data class or data element (*e.g.,* a new demographic element), we would need to initiate notice and comment rulemaking to incorporate that USCDI version change into the Program. Likewise, similar updates to standards included in our 2015 Edition final rule are made annually (or more frequently) by SDOs. In order to attempt to keep pace with such updates, which are published at different times of the year, ONC would need to continuously engage in rulemaking cycles, perhaps even more than once per year. We believe that the proposed Standards Version Advancement Process would allow for more advanced versions of standards and implementation specifications to be approved for use under the Program in a more timely and flexible manner that helps to ease the concerns stakeholders have reported. Stakeholder input throughout the Program's existence has informed ONC that updating large groupings of standards' versions while also adopting new standards through rulemakings that only occur about once every three years can create an artificial market impact in a number of ways. Such ''all-in-one'' updates affect all health IT developers and the vast majority of health care providers at the same time across all sectors rather than enabling a more incremental and market-based upgrade cycle in response to interoperability, business, and clinical needs.

The Standards Version Advancement Process and corresponding proposed revisions to §§ 170.550 and 170.555 would introduce two types of administrative flexibility for health IT developers participating in the Program. First, for those health IT developers with an existing certified Health IT Module, the Health IT Modules would be permitted to be upgraded (in the course of ongoing maintenance) to a new version of an adopted standard within the scope of the certification (without having to retest or recertify) so long as such version was approved by the National Coordinator for use in certification through the Standards Version Advancement Process. Second, for those health IT developers seeking to have a Health IT Module's initial certificate issued, the Health IT Module would be permitted to be presented for certification to a new version of an adopted standard so long as such version was approved by the National Coordinator through the Standards Version Advancement Process. This policy flexibility is similar to the flexibility we introduced several years ago for ''minimum standards'' code sets, but we would require ONC–ACBs to offer certification under the Standards Version Advancement Process to National-Coordinator-approved newer versions of all standards to which Real World Testing requirements apply.[97]

In order to ensure equitable treatment under the Program and in order for ONC to maintain the Program's overall integrity, each developer that chooses to leverage the proposed Standards Version Advancement Process Maintenance of Certification Program flexibilities would need to satisfy the following.

Health IT Developers Updating Already Certified Health IT

In instances where a health IT developer has certified a Health IT Module, including but not limited to instances where its customers are already using the certified Health IT Module, if the developer intends to update pursuant to the Standards Version Advancement Process election, the developer would be required to provide advance notice to all affected customers and its ONC–ACB: (a) Expressing its intent to update the software to the more advanced version of the standard approved by the National Coordinator through the Standards Version Advancement Process; (b) the developer's expectations for how the update will affect interoperability of the affected Health IT Module as it is used in the real world; and (c) whether the developer intends to continue to support the certificate for the existing Health IT Module version for some period of time and how long, or if the existing version of the Health IT Module certified to prior version(s) of applicable standards will be deprecated (*e.g.,* that the developer will stop supporting the earlier version of the module and request to have the certificate withdrawn). The notice would be required to be provided sufficiently in advance of the developer establishing its planned timeframe for implementation of the upgrade to the more advanced standard(s) version(s) in order to offer customers reasonable opportunity to ask questions and plan for the update. We request public comment on the minimum time prior to an anticipated implementation of an updated standard or implementation

[97] For purposes of clarity, we note that the Standards Version Advancement Process would not affect the established minimum standards code sets flexibility. Consistent with § 170.555, under the Program, health IT could continue to be certified or upgraded to a newer version of identified minimum standards code sets (*see* 80 FR 62612) than even the most recent one the National Coordinator had approved for use in the Program via the Standards Version Advancement Process unless the Secretary prohibits the use of the newer version for certification.

specification version update that should be considered reasonable for purposes of allowing customers, especially health care providers using the Health IT Module in their health care delivery operations, to adequately plan for potential implications of the update for their operations and their exchange relationships. We would also be interested to know if commenters believe that there are specific certification criteria, standards, characteristics of the certified Health IT Module or its implementation (such as locally hosted by the customer using it versus software-as-a-service type of implementation), or specific types or characteristics of customers that could affect the minimum advance notice that should be considered reasonable across variations in these factors.

We anticipate providing ONC–ACBs (and/or health IT developers) with a means to attribute this updated information to the listings on the CHPL for the Health IT Modules the ONC–ACB has certified, and propose to require in the Principles of Proper Conduct for ONC–ACBs that they are ultimately responsible for this information being made publicly available on the CHPL. We request public comment on any additional information about updated standards versions that may be beneficial to have listed with certified Health IT Modules on the CHPL.

We clarify that a health IT developer would be able to choose which of the updated standards versions approved by the National Coordinator for use in certification through the Standards Version Advancement Process the developer seeks to include in its updated certified Health IT Module and would be able to do so on an itemized basis. In other words, if the National Coordinator were to approve for use through the Standards Version Advancement Process several different new versions of adopted standards that affected different certification criteria within the scope of a certified Health IT Module, the developer would be able to just update one certification criterion to one or more of the applicable new standards and would not have to update its Health IT Module to all of the National Coordinator-approved new versions all at once in order to be able to take advantage of this proposed flexibility.

Health IT Developers Presenting a New Health IT Module for Certification and Leveraging the Standards Version Advancement Process

In instances where a health IT developer presents a Health IT Module for certification for which no prior certificate can serve as the basis for using the Standards Version Advancement Process, we propose that the health IT developer would be permitted to use and implement any and all of the newer versions of adopted standards the National Coordinator approves through the Standards Version Advancement Process. We have implemented this proposed policy through necessary adjustments to the way in which ONC–ACBs process certifications in § 170.550. We recognize that this proposed flexibility reflects certain programmatic and policy trade-offs. On one hand, a health IT developer would be permitted to use the most recent version of standards approved by the National Coordinator instead of having to build in potentially ''outdated'' standards just to get certified. On the other hand, the Program's testing infrastructure (which is now inclusive of government-developed and non-government-developed tools) may experience certain lag times in terms of when updated test tools to support the approved version advancements would be available to test Health IT Modules for certification purposes. As a result, we propose to provide the ability for ONC–ACBs to accept a developer self-declaration of conformity as to the use, implementation, and conformance to a newer version of a standard (including but not limited to implementation specifications) as sufficient demonstration of conformance in circumstances where the National Coordinator has approved a version update of a standard for use in certification through the Standards Version Advancement Process but an associated testing tool is not yet updated to test to the newer version. Again, we clarify that a health IT developer would be able to choose which National Coordinator-approved standard version(s) it seeks to include in a new or updated certified Health IT Module and would be able to do so on an itemized basis.

On balance, we believe that this programmatic flexibility and the potential interoperability improvements from the use of newer versions of standards outweighs the subsequent oversight challenges. Moreover, these oversight challenges can be mitigated by the Standards Version Advancement Process itself (*i.e.,* the National Coordinator not approving a new version if the Program or industry is not ready) and the corresponding Conditions of Certification that continue with the use of National Coordinator-approved new versions of adopted standards. We also believe that this approach will continue to hold developers accountable for, and shift the focus of Health IT Module performance demonstration to, real world testing for interoperability for deployed Health IT Modules. As described above, we understand the limitations of test methods used prior to certification and further emphasize the importance of continued conformance of Health IT Modules in the field. However, we request comment on specific Program impacts we should consider.

General Requirements Associated With Health IT Modules Certified Using the Standards Version Advancement Process

In all cases, regardless of whether a health IT developer is updating an existing certified Health IT Module or presenting a new Health IT Module for certification to new versions of adopted standards approved by the National Coordinator through the Standards Version Advancement Process, it would need to adhere to the following once it elects to takes advantage of this proposed flexibility:

- The developer would need to ensure its mandatory disclosures in § 170.523(k)(1) appropriately reflect its use of any National Coordinator-approved newer versions of standards.
- The developer would need to address and adhere to all Conditions of Certification and Maintenance of Certification requirements proposed that are otherwise be applicable to its certified Health IT Modules regardless of whether those Health IT Modules were certified to the exact same versions of adopted standards that are listed in the text of 45 CFR part 170 or National Coordinator-approved newer version(s) of the standard(s). For instance, the developer would need to ensure that its real world testing plan and performance included the National Coordinator-approved standards versions to which it is claiming conformance.

In terms of compliance with the real world testing Condition and Maintenance of Certification requirements, the attestations Condition and Maintenance of Certification requirements proposed in § 170.406, and for the purposes of ONC–ACB surveillance, we note that health IT developers would be accountable for maintaining all applicable certified Health IT Modules in accordance with approved versions of standards and implementation specifications that they voluntarily elect to use in their certified health IT. If, at any point after initial certification or updated certification for

a Health IT Module using the National Coordinator approved advanced versions of standards or implementation specifications, real world testing results do not demonstrate the Health IT Module's conformance to each applicable certification criterion had been achieved and maintained using the National Coordinator approved advanced version update of any applicable standard(s) and implementation specification(s), then the developer would not be allowed to claim or characterize the Health IT Module as conformant to the criterion using such standard version, and the standard or implementation specification version could not be indicated in the health IT Module's CHPL record as supported by any version release of the Health IT Module, until such time as they could demonstrate through ONC–ATL or results of real world testing that they had successfully upgraded the Health IT Module to fully conform to applicable certification criteria while incorporating the more advanced version of the standard. Non-conformities associated with the use of new versions of National Coordinator-approved standards would be found and enforced through the same Program rules just like they would be for non-conformities with the versions of adopted standards that are codified in regulation text. Further, we remind health IT developers that they would be required to make an attestation to their real world testing results, including (though not limited to) those that would be used to support use of new versions of National Coordinator-approved standards.

Advanced Version Approval Approach

Once a standard has been adopted for use in the Program through notice and comment rulemaking, ONC would undertake an annual, open and transparent process, including opportunity for public comment, to timely ascertain whether a more recent version of that standard or implementation specification should be approved for developers' voluntary use. ONC would identify updated versions of previously adopted standards and implementation specifications based on our own monitoring of market trends and interoperability needs, as well as input received from external stakeholders. Such external input may include, but would not be limited to, recommendations made by the Health Information Technology Advisory Committee as well as input received from SDOs.

ONC expects to use an expanded section of the Interoperability Standards Advisory (ISA) web platform to facilitate the public transparency and engagement process. At a particular time of the year (*e.g.,* early fall), ONC would post a list of new versions of adopted standards and implementation specifications that appear timely and appropriate for use within the Program (for the subsequent calendar year) along with accompanying descriptive context (*e.g.,* the types/nature of updates in the new version of a standard). ONC would then widely communicate to all members of the public that the list was available and make a general solicitation of comments to any and all interested parties for a period of 30 to 60 days. We would generally expect to receive comments on a range of issues related to the version of the standard under consideration, including its availability, testing tools, maturity, implementation burden, and overall impact on interoperability. Health IT developers, health information networks (HINs), and the health care organizations that purchase and use health IT are already familiar with the process of commenting through our existing ISA resource and we believe this process is well suited to support widespread engagement by all stakeholders. Similar to the ISA, we would expect to be open to receiving comments on newer versions of adopted standards throughout the year leading up to the formal comment period.

Once the formal comment period closes, ONC would review the comments and consider the potential impacts of a new version an adopted standard or implementation specification. We anticipate approving newer versions of adopted standards and implementation specifications based on several interdependent Program and market factors, such as its ability to enhance interoperability and overall compatibility with other adopted versions, how burdensome it would be to update to the newer version and the scope and scale of the changes, whether the new version would be required for reporting by a corresponding program (*e.g.,* CMS or CDC), the availability of test tools for the new version, and the new version's relationship to other adopted standards and any dependencies. Upon concluding our review and analysis, ONC would publish in this new ISA section a final list of National Coordinator-approved advanced versions that health IT developers could electively use consistent with the Standards Version Advancement Process.

Within this proposed approach, we expect that when it comes to a standard, the National Coordinator would identify version updates to an adopted standard consistent with that standard's name and version track. This method would provide long-term consistency for health IT developers in terms of the overall technical conformance requirements on which they will be focused.

With respect to adopted implementation specifications, we believe that more flexibility about the precise name and version track identifiers would be warranted given that implementation specifications are developed by market-driven industry consortia (*e.g.,* Argonaut project and Direct project stakeholders) as well as traditional SDOs. Similarly, authors of implementation specifications sometimes develop supplemental documents to the ''parent'' implementation specification or split the implementation specification to form newly titled materials. In any of these cases, the resulting implementation specification may—on its face—initially appear to bear no relation to a previously adopted implementation specification because of changes to its title, version naming, or numbering presentation. In reality, in many of these cases, the implementation specification retains substantially the same purpose(s) and thus represents a versioning update rather than amounting to a novel specification. Accordingly, regardless of its title and author, the National Coordinator would take into account whether any ''new'' implementation specification under consideration is more accurately characterized as novel to the Program or instead is a derivative work that is substantially a more advanced version of a previously adopted implementation specification(s). Stakeholders would also be able to comment on the same during the advanced version approval process described here.

The public listing of these National Coordinator determinations to approve version updates to already adopted standards and implementation specifications would serve as the single, comprehensive, and authoritative index of the versions of adopted standards and implementation specifications available for use under the Program. We note, however, that certain Program administration steps would need to occur (such as ONC–ACBs expanding the scope of their accreditations) after the National Coordinator has approved newer versions of adopted standards. As a result, there would likely be a temporary delay between the National Coordinator's approval decision and when certification to new standards versions under the Program would start.

We welcome comments on any and all aspects of our proposed standards

version approval process as an option available to developers through maintenance requirements as part of the real world testing Condition and Maintenance of Certification. This includes all aspects of our described approach to standards and implementation specification advanced version approval processes. We also invite comments on our proposal to allow in conjunction with this maintenance flexibility the opportunity for developers to elect to present health IT for initial testing and certification either to more advanced versions or the prior versions included in regulatory text as of the date the technology is presented.

Principle of Proper Conduct for ONC–ACB for All Real World Testing Proposals

We propose to include a new Principle of Proper Conduct for ONC–ACBs in § 170.523(p) that would require ONC–ACBs to review and confirm that applicable health IT developers submit real world testing plans and results in accordance with our proposals. We expect that ONC–ACBs would review the plans for completeness. Once completeness is confirmed, ONC–ACBs would provide the plans to ONC by December 15 and results to ONC by April 1. The December 15 date is the same date as the health IT developer requirement for submission of the real world testing plan. For purposes of the Program, this treats both regulated entities equally and permits them to work out a process that ensures all real world testing plans are submitted to the CHPL by December 15. For example, a health IT developer that is confident in its plan and does not anticipate any further certification, may submit its plan in July of the preceding year.

The submission of results, however, does not present the same dynamic of the potential need to work together to ensure the plan is complete. As such, we have proposed different dates. We would expect the developers to submit their results by January 31. We believe this would provide sufficient time for ONC–ACBs to review all plans and post them to the CHPL by April 1, including notifying ONC when the results were not in compliance with requirements. ONC would make both the plans and results publicly available via the CHPL. We note that ONC–ACBs will continue to be required to perform in-the-field surveillance of certified Health IT Modules and results of real world testing could be considered information to inform ONC–ACB surveillance activities.

Because we are proposing to allow health IT developers to implement National Coordinator-approved advanced versions of standards and implementation specifications in certified Health IT Modules through a developer self-declaration of conformity presented for certification if an associated testing tool is not yet updated to test to the newer version for the standards and implementation specification version updates they have chosen to use in the Program, we propose two requirements to ensure the public and ONC–ACBs have knowledge of the version of a standard that certified health IT meets. First, we propose to revise the Principle of Proper Conduct in § 170.523(m) to require ONC–ACBs to collect, no less than quarterly, all version updates made to standards successfully included in certified health IT per the requirements within the real world testing Condition of Certification Standards Version Advancement Process. This would ensure that ONC–ACBs are aware of the version of a standard that certified health IT meets for the purposes of surveillance and Program administration. Second, we propose (as discussed above), that a developer that chooses to avail itself of the Standards Version Advancement Process flexibility must address in its real world testing plans and results submissions the timeline and rollout of applicable version updates for standards and implementation specifications. This addition to § 170.523(m) along with existing requirements for weekly ONC–ACB CHPL reporting to versions of standards per § 170.523(f)(1)(xvii) would allow for timely updates to Health IT Module certificate information in the CHPL. Together with the requirements (discussed above) for developers' communication with their current and potential customers, we intend to ensure that the public and end-users have transparency into planned and actual standards and implementation specifications updates for their certified health IT.

In complement to the above requirements to ensure transparency for the public and end users, we propose in § 170.523(t) a new Principle of Proper Conduct for ONC–ACBs requiring them to ensure that developers seeking to take advantage of the Standards Version Advancement Process flexibility in § 170.405(b)(5) comply with the applicable requirements, and that the ONC–ACB both retain records of the timing and content of developers' § 170.405(b)(5) notices and timely post each notice's content publicly on the CHPL attributed to the certified Health IT Modules to which it applies.

We seek comment on the proposed additions to the Principles of Proper Conduct for ONC–ACBs. More specifically, we seek comment on whether ONC–ACBs should be required to perform an evaluation beyond a completeness check for the real world testing plans and results and the value versus the burden of such an endeavor.

6. Attestations

The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, provide to the Secretary an attestation to all the Conditions of Certification specified in the Cures Act, except for the ''EHR reporting criteria submission'' Condition of Certification. We propose to implement the Cures Act ''attestations'' requirements Condition of Certification in § 170.406. We also propose that, as part of the implementation of this statutory provision, health IT developers would attest, as applicable, to compliance with the Conditions and Maintenance of Certification requirements described in this section of the preamble and proposed in §§ 170.401 through 170.405.

We propose that, as a Maintenance of Certification requirement for the ''attestations'' Condition of Certification, health IT developers must submit their attestations every 6 months (*i.e.,* semiannually). We believe this would provide an appropriate ''attestation period'' to base any enforcement actions, such as by ONC under the Program or by the Office of the Inspector General under its Cures Act authority. We also believe this 6-month attestation period properly balances the need to support appropriate enforcement actions with the attestation burden placed on developers. We will determine when the first attestation will be due depending on when the final rule is published. We require attestations to be due twice a year, likely in the middle and end of the calendar year.

The process we plan to implement for providing attestations should minimize burden on health IT developers. First, we propose to provide a 14-day attestation period twice a year. For health IT developers presenting health IT for certification for the first time under the Program, we propose that they would be required to submit an attestation at the time of certification and then also comply with the semiannual attestation periods. Second, we would publicize and prompt developers to complete their attestation

during the required attestation periods. Third, we propose to provide a method for health IT developers to indicate their compliance, non-compliance with, or the inapplicability of each Condition and Maintenance of Certification requirement as it applies to all of their health IT certified under the Program for each attestation period. Last, we propose to provide health IT developers the flexibility to specify non-compliance per certified Health IT Module, if necessary. We note, however, that any non-compliance with the proposed Conditions and Maintenance of Certification requirements, including the ''attestations'' Conditions and Maintenance of Certification requirements, would be subject to ONC direct review, corrective action, and enforcement procedures under the Program. We refer readers to section VII.D of this preamble for discussion of proposed ONC direct review, corrective action, and enforcement procedures for the Conditions and Maintenance of Certification requirements under the Program.

We propose that attestations would be submitted to ONC–ACBs on behalf of ONC and the Secretary. We propose that ONC–ACBs would have two responsibilities related to attestations. One responsibility we propose in § 170.523(q) is that an ONC–ACB must review and submit the health IT developers' attestations to ONC. ONC would then make the attestations publicly available through the CHPL. The other responsibility we propose in § 170.550(l) is that before issuing a certification, an ONC–ACB would need to ensure that the health IT developer of the Health IT Module has met its responsibilities related to the Conditions and Maintenance of Certification requirements as solely evidenced by its attestation. For example, if a health IT developer with an active certification under the Program indicated non-compliant designations in their attestation but is already participating in a corrective action plan under ONC direct review to resolve the non-compliance, certification would be able to proceed while the issue is being resolved.

We welcome comments on the proposed attestations Condition and Maintenance of Certification requirements, including the appropriate frequency and timing of attestations. We also welcome comments on the proposed responsibilities for ONC–ACBs related to the attestations of Condition and Maintenance of Certification requirements.

7. EHR Reporting Criteria Submission

The Cures Act specifies that health IT developers be required, as a Condition and Maintenance of Certification under the Program, to submit reporting criteria on certified health IT in accordance with the EHR reporting program established under section 3009A of the PHSA, as added by the Cures Act. We have not yet established an EHR reporting program. Once ONC establishes such program, we will undertake future rulemaking to propose and implement the associated Condition and Maintenance of Certification requirement(s) for health IT developers.

C. Compliance

The proposed Maintenance of Certification requirements discussed above do not necessarily define all the outcomes necessary to meet the Conditions of Certification. Rather, they provide preliminary or baseline evidence toward measuring whether a Condition is being met. Thus, ONC could determine that a Condition of Certification is not being met through reasons other than the Maintenance of Certification requirements. For example, meeting the proposed Maintenance of Certification requirement that requires a health IT developer to not establish or enforce any contract or agreement that contravenes the Communications Condition of Certification does not excuse a health IT developer from meeting all the requirements specified in the proposed Communications Condition of Certification. This is analogous to clarifications ONC has previously provided about certification criteria requirements whereby testing prior to certification sometimes only tests a subset of the full criterion's intended functions and scope. However, for compliance and surveillance purposes, we have stated that ONC and its ONC–ACBs will examine whether the certified health IT meets the full scope of the certification criterion rather than the subset of functions it was tested against (80 FR 62709–10).

D. Enforcement

The Cures Act affirms ONC's role in using certification to improve health IT's capabilities for the access, use, and exchange of electronic health information. The Cures Act provides this affirmation through expanded certification authority for ONC to establish Conditions and Maintenance of Certification requirements for health IT developers that go beyond the certified health IT itself. The new Conditions and Maintenance of Certification provisions in section 4002 of the Cures Act focus on the actions and business practices of health IT developers (*e.g.,* information blocking and appropriate access, use, and exchange of electronic health information) as well as technical interoperability of health IT (*e.g.,* APIs and real world testing). Furthermore and equally important, section 4002 of the Cures Act provides that the Secretary of HHS may encourage compliance with the Conditions and Maintenance of Certification requirements and take action to discourage noncompliance. As discussed in the 2015 Edition final rule, ONC is not limited to enforcing Program compliance solely through those requirements expressed in certification criteria adopted under the Program (80 FR 62710; see also 81 FR 72412). Certification under the Program also relies on a health IT developer's compliance with Program requirements that ensure the basic integrity and effectiveness of the Program, which is further stressed through the addition of the Conditions and Maintenance of Certification requirements in the Cures Act (referred to jointly as the ''Conditions and Maintenance of Certification'' in this section of the preamble).

Given these considerations, we propose a general enforcement approach outlining a corrective action process for ONC to review potential or known instances where a Condition or Maintenance of Certification requirement has not been or is not being met by a health IT developer under the Program, including the requirement for a health IT developer to attest to meeting the Conditions and Maintenance of Certification. Table 2 below provides an overview of the proposed approach to ONC enforcement of the Conditions and Maintenance of Certification. We provide more specific proposals following Table 2.

TABLE 2—PROPOSED APPROACH FOR ENFORCEMENT OF THE CONDITIONS AND MAINTENANCE OF CERTIFICATION

Proposed regulatory text	Condition of certification	Opportunity for developer to take corrective action	Consequences of not taking appropriate corrective action	Opportunity for developer to appeal ONC determination to terminate or ban
§ 170.401	Information Blocking	Yes	Certification ban of all of a developer's certified Health IT Modules.	Yes.
§ 170.402	Assurances.			
§ 170.403	Communications.		ONC may also consider termination of Health IT Module certificates if there is a nexus between the developer's practices and a certified Health IT Module.	
§ 170.404	APIs.			
§ 170.405	Real World Testing.			
§ 170.406	Attestations.			

1. ONC Direct Review of the Conditions and Maintenance of Certification Requirements

We propose to utilize the processes previously established for ONC direct review of certified health IT in the EOA final rule (81 FR 72404) and codified in §§ 170.580 and 170.581 for the enforcement of the Conditions and Maintenance of Certification. We propose this approach for multiple reasons. First, these processes were established to address non-conformities with Program requirements. Conditions and Maintenance of Certification are proposed to be adopted as Program requirements and, as such, any noncompliance with the Conditions and Maintenance of Certification would constitute a Program non-conformity. Second, health IT developers are familiar with the ONC direct review provisions as they were established in October 2016. Third, §§ 170.580 and 170.581 provide thorough and transparent processes for working with health IT developers through notice and corrective action to remedy Program non-conformities. Last, the direct review framework provides equitable opportunities for health IT developers to respond to ONC actions and appeal certain ONC determinations.

2. Review and Enforcement Only by ONC

We propose to retain use of the term ''direct review'' as previously adopted in the EOA final rule to continue to distinguish actions ONC takes to directly review certified health IT or health IT developers' actions in comparison to an ONC–ACB's review of certified health IT under surveillance. We propose, however, that ONC would be the sole party responsible for enforcing compliance with the Conditions and Maintenance of Certification. The Conditions and Maintenance of Certification focus on health IT developer behavior and actions in addition to the certified Health IT Module. ONC is more familiar with the behavioral requirements based on its expertise and experience. Conversely, ONC–ACBs are generally more suited, based on their accreditation and current responsibilities, to address non-conformities with technical and other Program requirements. ONC also has the necessary resources and the ability to coordinate with other agencies to enforce the Conditions and Maintenance of Certification, such as with the ''information blocking'' Condition of Certification (proposed § 170.401). Further, ONC enforcement would provide more predictability and consistency, which would likely benefit stakeholders in matters related to API fees and information blocking. We do, however, discuss below the scope of ONC–ACB surveillance as it relates to ONC's proposed enforcement of the Conditions and Maintenance of Certification.

3. Review Processes

We propose to substantially adopt the processes as they are currently codified in §§ 170.580 and 170.581 for ONC's review and enforcement of the Conditions and Maintenance of Certification, but propose certain revisions and additions to the processes to properly incorporate the proposed Conditions and Maintenance of Certification and effectuate Congressional intent. These revisions and additions include renaming and restructuring headings for clarity, which we do not discuss below.

a. Initiating Review and Health IT Developer Notice

We propose to fully incorporate the review of the Conditions and Maintenance of Certification into the provisions of § 170.580(a) and (b). We propose in § 170.580(a)(iii) that if ONC has a reasonable belief that a health IT developer has not complied with a Condition of Certification, then it *may* initiate direct review. Similarly, we propose in § 170.580(b)(1) and (2) that ONC may issue the health IT developer a notice of potential non-conformity or notice of non-conformity and provide the health IT developer an opportunity to respond with an explanation and written documentation, including any information ONC requests. These processes, including relevant timeframes, are specified in § 170.580(b).

i. Complaint Resolution

We note and recommend that customers and end-users first work with their health IT developers to resolve any issues of potential non-compliance with the Conditions and Maintenance of Certification as prior Program experience has shown that many issues can be resolved at this step. If the issue cannot be resolved, we then recommend the end-user contact the ONC–ACB. However, as discussed above and in section VII.D.5 below, the ONC–ACB purview for certified health IT generally applies to certified capabilities and limited requirements of developer business practices. If neither of these pathways resolves the issue, end-users may provide feedback to ONC via the Health IT Feedback Form.[98]

ii. Method of Correspondence With Health IT Developers

Section 170.505 states that correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified. In the EOA final rule, we signaled our intent to send notices of potential non-conformity, non-conformity, suspension, proposed termination, and termination via certified mail (81 FR 72429). However, in accordance with § 170.505, we propose that email should be the default mode of correspondence for direct review of non-compliance with the Conditions and Maintenance of Certification.

[98] *https://www.healthit.gov/form/healthit-feedback-form.*

Under the EOA final rule, ONC can initiate direct review of certified health IT in limited circumstances, namely when there is a reasonable belief that the certified health IT may be causing or contributing to serious risks to public health or safety or suspected non-conformities present practical challenges that may prevent an ONC–ACB from effectively investigating or responding to the suspected non-conformity. In contrast, we propose in this proposed rule to enable ONC to initiate direct review to address a health IT developer's conduct under the Conditions and Maintenance of Certification requirements in addition to non-conformities in certified health IT. This proposal would create an expanded set of circumstances for ONC to conduct direct review. Accordingly, the type and extent of review by ONC could vary significantly based on the complexity and severity of each fact pattern. For instance, ONC may be able to address certain non-conformities under the Conditions and Maintenance of Certification quickly and with minimal effort (*e.g.,* failure to make public a documentation hyperlink), while others may be more complex and require additional time and effort (*e.g.,* violation of API fee prohibitions). Considering this wide range of potential non-conformities under the Conditions and Maintenance of Certification, we believe it is appropriate for ONC to retain discretion to decide, on a case-by-case basis, when to go beyond the provisions of § 170.505 in providing notices and correspondence for non-compliance with the Conditions and Maintenance of Certification.

We solicit comment on the nature and types of non-conformities with the Conditions and Maintenance of Certification requirements that ONC should consider in determining the method of correspondence. We also solicit comment on whether the type of notice should affect the method of correspondence and whether certain types of notices under direct review should be considered more critical than others, thus requiring a specific method of correspondence.

b. Relationship With ONC–ACBs and ONC–ATLs

Section 170.580(a)(3) outlines ONC direct review in relation to the roles of ONC–ACBs and ONC–ATLs, which we propose to revise to incorporate Conditions and Maintenance of Certification. We note that we provide situational examples below in section VII.D.5 ''Effect on Existing Program Requirements and Processes'' regarding ONC direct review and the role of an ONC–ACB. As finalized in the EOA final rule and per § 170.580(a)(3)(v), we remind readers that ONC may refer the applicable part of its review of certified health IT to the relevant ONC–ACB(s) if ONC determines this would serve the effective administration or oversight of the Program (81 FR 72427–72428).

c. Records Access

We propose to revise § 170.580(b)(3) to ensure that ONC, or third parties acting on its behalf, has access to the information necessary to enforce the Conditions and Maintenance of Certification. As specified in § 170.580(b)(1)(ii)(A)(*2*), (b)(2)(ii)(A)(*2*) and (b)(3), in response to a notice of potential non-conformity or notice of non-conformity, ONC must be granted access to, and have the ability to share within HHS, with other federal agencies, and with appropriate entities, all of a health IT developers' records and technology related to the development, testing, certification, implementation, maintenance, and use of a health IT developers' certified health IT; and any complaint records related to the certified health IT. ''Complaint records'' include, but are not limited to issue logs and help desk tickets (81 FR 72431). We propose to supplement these requirements with a requirement that a health IT developer make available to ONC, and third parties acting on its behalf, records related to marketing and distribution, communications, contracts, and any other information relevant to compliance with any of the Conditions and Maintenance of Certification or other Program requirements. This information would assist in reviewing allegations that a health IT developer violated, for example, the ''prohibit and restrict communications'' Condition of Certification. Further, it is possible that multiple Conditions and Maintenance of Certification may be implicated under a review, and thus ONC believes it is appropriate to require a developer make available to ONC *all* records and other relevant information concerning all the Conditions and Maintenance of Certification and Program requirements to which it and its Health IT Modules are subject.

If ONC determined that a health IT developer was not cooperative with the fact-finding process, we propose ONC would have the ability to issue a certification ban and/or terminate a certificate (*see* proposed § 170.581 discussed below and § 170.580(f)(1)(iii)(A)(*1*)).

We understand that health IT developers may have concerns regarding the disclosure of proprietary, trade secret, competitively sensitive, or other confidential information. As we stated in the EOA final rule (81 FR 72429), ONC would implement appropriate safeguards to ensure, to the extent permissible with federal law, that any proprietary business information or trade secrets ONC may encounter by accessing the health IT developer's records, other information, or technology, would be kept confidential by ONC or any third parties working on behalf of ONC. However, a health IT developer would not be able to avoid providing ONC access to relevant records by asserting that such access would require it to disclose trade secrets or other proprietary or confidential information. Therefore, health IT developers must clearly mark, as described in HHS Freedom of Information Act regulations at 45 CFR 5.65(c), any information they regard as trade secret or confidential commercial or financial information which they seek to keep confidential prior to disclosing the information to ONC or any third party working on behalf of ONC.

d. Corrective Action

We propose that if ONC determines that a health IT developer is noncompliant with a Condition of Certification (*i.e.,* a non-conformity), ONC would work with the health IT developer to establish a corrective action plan (CAP) to remedy the issue through the processes specified in § 170.580(b)(2)(ii)(A)(*4*) and (c). We note that a health IT developer may be in noncompliance with more than one Condition of Certification. In such cases, ONC will follow the proposed compliance enforcement process for each Condition of Certification accordingly, but may also require the health IT developer to address all violations in one CAP for efficiency of process. We also propose, as we currently do with CAPs for certified health IT, to list health IT developers under a CAP on ONC's website.

e. Certification Ban and Termination

We propose in § 170.581 that if a health IT developer under ONC direct review for non-compliance with a Condition of Certification failed to work with ONC or was otherwise noncompliant with the requirements of the CAP and/or CAP process, ONC could issue a certification ban for the health IT developer (and its subsidiaries and successors). A certification ban, as it currently does for other matters under § 170.581, would prohibit prospective certification activity by the health IT developer.

ONC would also consider termination [99] of the certificate(s) of the affected Health IT Module(s) should the health IT developer fail to work with ONC or is otherwise noncompliant with the requirements of the CAP and/or CAP process (*see* proposed § 170.580(f)(1)(iii)). ONC may consider termination if there is a nexus between the developer's actions or business practices and certified Health IT Module(s) (*see* proposed § 170.580(f)(1)(iii)). For example, ONC may determine that a health IT developer is violating a Condition of Certification due to a clause in its contracts that prevents its users from sharing or discussing technological impediments to information exchange. In this example, the health IT developer's conduct would violate the ''prohibiting or restricting communication'' Condition of Certification proposed in § 170.403. If the same conduct were also found to impair the functionality of the certified Health IT Module (such as by preventing the proper use of certified capabilities for the exchange of EHI), ONC may determine that a nexus exists between the developer's business practices and the functionality of the certified Health IT Module, and may consider termination of the certificates of that particular Health IT Module under the proposed approach.

We propose this approach, which allows ONC to initiate a certification ban and/or certificate termination under certain circumstances, to ensure that health IT developers are acting in accordance with the Conditions and Maintenance of Certification. However, we stress that our first and foremost priority is to work with health IT developers to remedy any noncompliance with Conditions and Maintenance of Certification through a corrective action process before taking further action. This emphasizes ONC's desire to promote and support health IT developer compliance with the Conditions and Maintenance of Certification and ensure that certified health IT is compliant with Program requirements in order to foster an environment where EHI is exchanged in an interoperable way.

ONC does not believe that noncompliance with a Condition of Certification should always result in the termination of the certificate of one or more of a developer's Health IT Modules for a few reasons. A violation of a Condition of Certification may relate solely to health IT developer business practices or actions that do not affect the Health IT Module's conformance to the requirements of the certification criteria. In this case, termination of the certification could unfairly and negatively affect a provider's ability to use the Health IT Module for participation in CMS programs that require certification because the Health IT Module itself is functioning in accordance with the technical requirements of its certificate.[100] As such, ONC would carefully consider on a case-by-case basis the appropriateness of termination of a Health IT Module's certification(s) based on the specific circumstances of the noncompliance with the Condition of Certification. The proposed enforcement approach balances the above stated goals and provides an outlined process that can be consistently followed.

In considering whether termination of a Health IT Module's certificate(s) and/or a certification ban is appropriate, ONC will consider factors including, but not limited to: Whether the health IT developer has previously been found in noncompliance with the Conditions and Maintenance of Certification or other Program requirements; the severity and pervasiveness of the noncompliance, including the effect of the noncompliance on widespread interoperability and health information exchange; the extent to which the health IT developer cooperates with ONC to review the noncompliance; the extent of potential negative impact on providers who may seek to use the certified health IT to participate in CMS programs; and whether termination and/or a certification ban is necessary to ensure the integrity of the certification process.

As under § 170.580(f)(2), ONC would provide notice of the termination to the health IT developer, including providing reasons for, and information supporting, the termination and instructions for appealing the termination. We propose to add similar notice provisions to § 170.581 for certification bans issued under ONC direct review for non-compliance with the Conditions and Maintenance of Certification, which would also include instructions for requesting reinstatement. In this regard, we propose to apply the current reinstatement procedures under § 170.581 to Conditions and Maintenance of Certification bans, but with an additional requirement that the health IT developer has resolved the non-compliance with the Condition of Certification. In sum, a health IT developer could seek ONC's approval to re-enter the Program and have the certification ban lifted if it demonstrates it has resolved the noncompliance with the Condition of Certification and ONC is satisfied that all affected customers have been provided appropriate remediation.

For clarity, a health IT developer would have an opportunity to appeal an ONC determination to issue a certification ban and/or termination IT resulting from a non-conformity with a Condition of Certification as discussed below and/or seek reinstatement in the Program and have the certification ban lifted. To note, we propose to make terminations effective consistent with current § 170.580(f)(2)(iii) and similarly for certification bans (*see* proposed § 170.581(c)). We seek comment on whether ONC should:

- Impose a minimum certification ban length before a health IT developer can request ONC remove the ban for health IT developers who are noncompliant with a Condition of Certification more than once (*e.g.,* a minimum six months for two instances, a minimum of one year for three instances).
- Consider additional factors for a certification ban and/or the termination of a health IT developer's certified health IT resulting from a non-conformity with a Condition of Certification.

f. Appeal

We propose to provide a health IT developer an opportunity to appeal an ONC determination to issue a certification ban and/or termination resulting from a non-conformity with a Condition of Certification and would follow the processes specified in § 170.580(g). As such, we propose to revise § 170.580(g) to include ONC direct review of the Conditions and Maintenance of Certification.

g. Suspension

Section 170.580 includes a process for suspending the certification of a Health IT Module at any time if ONC has a reasonable belief that the certified health IT may present a serious risk to public health and safety. While this will

[99] As noted in the EOA final rule, ''termination'' means an ONC action to ''terminate'' or ''revoke'' the certification status of a Complete EHR or Health IT Module. (81 FR 72443).

[100] Note that, in this example, an ONC–ACB may investigate the technical functionalities of the Health IT Module against its certificate and perform surveillance under § 170.556 separate from ONC's process to enforce compliance with the Conditions of Certification. If under ONC–ACB surveillance, a health IT developer does not adequately or timely fulfill a corrective action plan, the ONC–ACB may suspend and withdraw the Health IT Module's certificate. The expectations of ONC–ACB duties as relates to ONC's enforcement of the conditions of certification are described further in the preamble.

remain the case for certified health IT under ONC direct review (*i.e.,* suspension of certification is always available under ONC direct review when the certified health IT presents a serious risk to public health and safety), we do not believe such circumstances would apply to noncompliance with the Conditions of Certification. Further, we believe the more streamlined processes proposed for addressing noncompliance with Conditions and Maintenance of Certification alleviates the need to proceed through a suspension process. Therefore, we do not propose to apply the suspension processes under § 170.580 to our review of the Conditions of Certification. We welcome comments on this proposal, including reasons for why we should apply suspension processes to the Conditions of Certification as part of a subsequent final rule.

h. Proposed Termination

Section 170.580 includes an intermediate step between a developer failing to take appropriate and timely corrective action and termination of a certified Health IT Module's certificate, called ''proposed termination'' (*see* § 170.580(e) and 81 FR 72437)). We propose to *not* include this step when a health IT developer fails to take appropriate and timely corrective action for noncompliance with a Condition of Certification. Rather, as discussed above, ONC may proceed directly to issuing a certification ban or notice of termination if it determines a certification ban and/or termination are appropriate per the considerations discussed above. The Conditions and Maintenance of Certification include requirements of developer business practices and actions for which, as previously discussed, noncompliance with the Conditions and Maintenance of Certification in these arenas are likely to undermine the integrity of the Program and impede widespread interoperability and information exchange. As such, ONC believes it is appropriate and consistent with the Cures Act to proceed immediately to a certification ban and/or termination of the affected certified Health IT Modules' certificates if a developer does not take appropriate and timely corrective action. A certification ban and/or termination are appropriate disincentives for noncompliance with the Conditions and Maintenance of Certification.

4. Public Listing of Certification Ban and Terminations

We propose to publicly list health IT developers and certified Health IT Modules on ONC's website that are subject to a certification ban and/or have been terminated, respectively, for noncompliance with a Condition of Certification or for reasons already specified in § 170.581. We currently take this same approach for health IT with terminated certifications (*see* 81 FR 72438). Public listing serves to discourage noncompliance with Conditions and Maintenance of Certification, other Program requirements, remediation of non-conformities, and cooperation with ONC and the ONC–ACBs. It also serves to provide notice to all ONC–ATLs, ONC–ACBs, public and private programs requiring the use of certified health IT, and consumers of certified health IT of the status of certified health IT and health IT developers operating under the Program.

We seek comment on this proposal, including input on the appropriate period of time to list health IT developers and affected certified Health IT Modules on healthit.gov. For example, if a developer sought and received reinstatement under the Program (and lifting of the certification ban), should the health IT developer no longer be listed on the ONC website? Alternatively, should we list health IT developers who have been subject to the certification ban under § 170.581 for a certain period of time beyond the active ban, including indefinitely (*e.g.,* with the timeframe when the ban was active)?

5. Effect on Existing Program Requirements and Processes

The Cures Act introduces new Conditions and Maintenance of Certification that encompass technical and functional requirements of health IT and new actions and business practice requirements for health IT developers, which ONC proposes to adopt in subpart D of Part 170. The pre-Cures Act structure and requirements of the Program provide processes to enforce compliance with technical and functional requirements of certified health IT, and to a more limited extent, requirements for the business practices of health IT developers (see, *e.g.,* 45 CFR 170.523(k)(1)) under subparts C (Certification Criteria for Health Information Technology) and E (ONC Health IT Certification Program) of Part 170. ONC–ACBs are required to perform surveillance on certified Health IT Modules and may investigate reported alleged non-conformities with Program requirements under subparts A, B, C, and E with the ultimate goal to work with the health IT developer to correct the non-conformity. Under certain situations, such as unsafe conditions or impediments to ONC–ACB oversight, ONC may directly review certified health IT to determine whether it conforms to the requirements of the Program (*see* § 170.580 and the EOA final rule at 81 FR 72404). These avenues for investigating non-conformities with certified Health IT Modules will continue to exist under the Program and generally focus on functionality and performance of certified health IT or more limited requirements of business practices of health IT developers found in subparts A, B, C and E of Part 170, respectively. Thus, there may be instances where one or more Conditions and Maintenance of Certification are not being or have not been met that also relate to certified Health IT Modules non-conformities under subparts A, B, C and E. Under these situations, ONC could in parallel implement both sets of processes—existing processes to investigate Health IT Module non-conformities and the proposed process to enforce compliance with the Conditions and Maintenance of Certification.

We again note that under the proposed enforcement approach, only ONC would have the ability to determine whether a Condition or Maintenance of Certification requirement per subpart D has been or is being met. We propose to delineate the scope of an ONC–ACB's requirements to perform surveillance on certified Health IT Modules as related only to the requirements of subparts A, B, C and E of Part 170. Table 3 below further illustrates the proposed difference in scope of review activities between ONC–ACBs and ONC. Given our proposed approach that would authorize solely ONC to determine whether a Condition or Maintenance of Certification requirement per subpart D has been or is being met, we propose to add a new Principle of Proper Conduct for ONC–ACBs in § 170.523(s) that would require ONC–ACBs to report to ONC, no later than a week after becoming aware, any information that could inform whether ONC should exercise direct review for noncompliance with a Condition of Certification or any matter within the scope of ONC direct review. We believe this is appropriate because ONC–ACBs receive complaints and other information about certified Health IT Modules through their own channels; as this information may relate to potential noncompliance with the Conditions and Maintenance of Certification or other matters within the scope of ONC direct review, ONC should be made aware of this information.

TABLE 3—SCOPE OF ONC–ACB SURVEILLANCE AND ONC DIRECT REVIEW FOR PROPOSED ENFORCEMENT APPROACH FOR CONDITIONS AND MAINTENANCE OF CERTIFICATION

Condition of certification	ONC–ACB purview for surveillance per 170.556	ONC purview for enforcement per 170.580 and 170.581
170.401: Information Blocking	Only as it relates to Subparts A, B, C and E of Part 170	All of 170.401.
170.402: Assurances	Only as it relates to Subparts A, B, C and E of Part 170, including the certification criterion in § 170.315(b)(10) ''EHI export''.	All of 170.402.
170.403: Communications	Only as it relates to Subparts A, B, C and E of Part 170	All of 170.403.
170.404: APIs	Only as it relates to Subparts A, B, C and E of Part 170, including the certification criterion in § 170.315(g)(10).	All of 170.404.
170.405: Real World Testing	Only as it relates to Subparts A, B, C and E of Part 170	All of 170.405.
170.406: Attestations	Only as it relates to Subparts A, B, C and E of Part 170	All of 170.406.

For example and further illustration purposes, ONC may receive a complaint of information blocking alleging that a health IT developer has limited the ability to receive secure Direct messages from users of a competing developer's EHR. The complaint alleges the certified health IT drops the incoming message without alerting the user that a message was ever received. ONC would consider the information blocking concerns (proposed § 170.401) as well as the potential safety concerns presented by dropped messages associated with certified functionality of the 2015 Edition ''transitions of care'' certification criterion (§ 170.315(b)(1)) and standards for the secure Direct messaging in its review. For the potential safety concerns, ONC would be exercising its authority to review certified health IT that may be causing or contributing to conditions that present a serious risk to public health or safety under § 170.580(a)(2)(i). In contrast, the ONC–ACB would not be responsible for reviewing the information blocking or safety concerns directly, but it *would* be responsible for assessing whether surveillance needs to be performed on the certified health IT for the functionality in the 2015 Edition ''transitions of care'' certification criterion (§ 170.315(b)(1)) and the 2015 Edition ''Direct Project'' certification criterion (§ 170.315(h)(1)), as these requirements are found within subpart C of Part 170 and could be implicated based on the complaint.

To provide another example, an ONC–ACB could receive complaints from users that a developer's certified health IT does not support the FHIR DSTU 2 standard and associated API resource collection in health (ARCH Version 1) as required in the proposed new 2015 Edition certification criterion § 170.315(g)(10) (proposed under subparts B and C).The respective ONC–ACB(s) responsible for the certification of the certified health IT could surveil this health IT under the requirements of § 170.556 (under subpart E). Additionally, ONC could follow the CAP process under § 170.580(c) to enforce the associated ''API'' Condition of Certification proposed in § 170.404(a)(2). During the course of the ONC–ACB surveillance, the ONC–ACB subsequently discovers the developer has implemented the FHIR DSTU 2 standard and associated resources in such as a way that the patient's historical medications are being accessed, but not the patient's current medications. The ONC–ACB would notify ONC of its findings as it relates to a Condition of Certification under subpart D and pursue its own corrective action process under the surveillance requirements of § 170.556. Once ONC receives information regarding the complaints from the ONC–ACB, we could consider the potential safety risks for providers using the developer's API to access new or referred patients' medical information for diagnostic and treatment purposes. In this example, ONC could review both the certified health IT and the developer action under § 170.580, which is proposed to be expanded to account for developer actions under the Conditions and Maintenance of Certification (*see* proposed § 170.580(a)(2)(iii)) in addition to ONC's direct investigation of certified health IT for potential safety risks (*see* § 170.580(a)(2)(i)).

6. Concurrent Enforcement by the Office of Inspector General

We clarify that the enforcement approach described in this proposal would apply to ONC's administration of the Conditions and Maintenance of Certification and other requirements under the Program but would not apply to other agencies or offices that have independent authority to investigate and take enforcement action against a health IT developer of certified health IT. Notably, section 3022(b)(1)(A)(ii) of the PHSA, as added by the Cures Act, authorizes the OIG to investigate claims that a health IT developer of certified health IT has engaged in information blocking, which is defined by section 3022(a)(1) of the PHSA subject to reasonable and necessary activities identified by the Secretary as exceptions to the definition as proposed at part 171 (see section VIII. of this proposed rule). Additionally, section 3022(b)(1)(A)(i) authorizes OIG to investigate claims that a health IT developer of certified health IT has submitted a false attestation under the Condition of Certification described at section 3001(c)(5)(D)(vii). We emphasize that ONC's and OIG's respective authorities under the Cures Act (and in general) are independent and that either or both offices may exercise those authorities at any time.

We anticipate, however, that ONC and OIG may coordinate their respective enforcement activities, as appropriate, such as by sharing information about claims or suggestions of possible information blocking or false attestations (including violations of Conditions and Maintenance of Certification that may indicate that a developer has falsely attested to meeting a condition). Therefore, we propose that we may coordinate our review of a claim of information blocking with the OIG or defer to the OIG to lead a review of a claim of information blocking. In addition, we propose that we may rely on OIG findings to form the basis of a direct review action.

7. Applicability of Conditions and Maintenance of Certification Requirements for Self-Developers

The final rule establishing ONC's Permanent Certification Program, ''Establishment of the Permanent Certification for Health Information'' (76 FR 1261), addresses self-developers. The language in the final rule describes the concept of ''self-developed'' as referring to a Complete EHR or EHR Module designed, created, or modified by an entity that assumed the total costs for

testing and certification and that will be the primary user of the health IT (76 FR 1300). Therefore, self-developers differ from other health IT developers in that their products are not made commercially available and they do not have customers. While we propose that all general Conditions and Maintenance of Certification requirements apply to such developers, we also seek comment on which *aspects* of the Conditions and Maintenance of Certification requirements may not be applicable to self-developers. For example, when considering the Communications Condition of Certification, a self-developer of health IT may not have customer contracts, but could have other agreements in place, such as NDAs, that would be subject to the Condition of Certification.

VIII. Information Blocking

A. Statutory Basis

Section 4004 of the Cures Act added section 3022 of the PHSA (42 U.S.C. 300jj–52, ''the information blocking provision''). Section 3022(a)(1) of the PHSA defines practices that constitute information blocking when engaged in by a health care provider, or a health information technology developer, exchange, or network. Section 3022(a)(3) authorizes the Secretary to identify, through notice and comment rulemaking, reasonable and necessary activities that do not constitute information blocking for purposes of the definition set forth in section 3022(a)(1). We propose to establish seven exceptions to the information blocking definition, each of which would define certain activities that would not constitute information blocking for purposes of section 3022(a)(1) of the PHSA because they are reasonable and necessary to further the ultimate policy goals of the information blocking provision. We also propose to interpret or define certain statutory terms and concepts that are ambiguous, incomplete, or provide the Secretary with discretion, and that we believe are necessary to carry out the Secretary's rulemaking responsibilities under section 3022(a)(3).

B. Legislative Background and Policy Considerations

In this section, we outline the purpose of the information blocking provision and related policy and practical considerations that we considered in identifying the reasonable and necessary activities that are proposed as exceptions to the definition of information blocking described subsequently in section VIII.D of this preamble.

1. Purpose of the Information Blocking Provision

The information blocking provision was enacted in response to concerns that some individuals and entities are engaging in practices that unreasonably limit the availability and use of electronic health information (EHI) for authorized and permitted purposes. These practices undermine public and private sector investments in the nation's health IT infrastructure and frustrate efforts to use modern technologies to improve health care quality and efficiency, accelerate research and innovation, and provide greater value and choice to health care consumers.

The nature and extent of information blocking has come into sharp focus in recent years. In 2015, at the request of Congress, we submitted a Report on Health Information Blocking [101] (''Information Blocking Congressional Report''), in which we commented on the then current state of technology and of health IT and health care markets. Notably, we observed that prevailing market conditions create incentives for some individuals and entities to exercise their control over EHI in ways that limit its availability and use.

Since that time, we have continued to receive complaints and reports of information blocking from patients, clinicians, health care executives, payers, app developers and other technology companies, registries and health information exchanges, professional and trade associations, and many other stakeholders. ONC has listened to and reviewed these complaints and reports, consulted with stakeholders, and solicited input from our federal partners in order to inform our proposed information blocking policies. Stakeholders described discriminatory pricing policies that have the obvious purpose and effect of excluding competitors from the use of interoperability elements. Many of the industry stakeholders who shared their perspectives with us in listening sessions, including several health IT developers of certified health IT, condemned these practices and urged us to swiftly address them. Our engagement with stakeholders confirms that, despite significant public and private sector efforts to improve interoperability and data accessibility, adverse incentives remain and continue to undermine progress toward a more connected health system.

Based on these economic realities and our first-hand experience working with the health IT industry and stakeholders, in the Information Blocking Congressional Report, we concluded that information blocking is a serious problem and recommended that Congress prohibit information blocking and provide penalties and enforcement mechanisms to deter these harmful practices.

Recent empirical and economic research further underscores the intractability of this problem and its harmful effects. In a national survey of health information organizations, half of respondents reported that EHR developers routinely engage in information blocking, and a quarter of respondents reported that hospitals and health systems routinely do so. The survey reported that perceived motivations for such conduct included, for EHR vendors, maximizing short-term revenue and competing for new clients, and for hospitals and health systems, strengthening their competitive position relative to other hospitals and health systems.[102] Other research suggests that these practices weaken competition among health care providers by limiting patient mobility, encouraging consolidation, and creating barriers to entry for developers of new and innovative applications and technologies that enable more effective uses of clinical data to improve population health and the patient experience.[103]

The information blocking provision provides a comprehensive response to these concerns. The information blocking provision defines and creates possible penalties and disincentives for

[101] ONC, Report to Congress on Health Information Blocking (Apr. 2015), *https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf* [hereinafter ''Information Blocking Congressional Report''].

[102] *See, e.g.,* Julia Adler-Milstein and Eric Pfeifer, *Information Blocking: Is It Occurring And What Policy Strategies Can Address It?,* 95 Milbank Quarterly 117, 124–25 (Mar. 2017), *available at http://onlinelibrary.wiley.com/doi/10.1111/1468-0009.12247/full.*

[103] *See, e.g.,* Martin Gaynor, Farzad Mostashari, and Paul B. Ginsberg, *Making Health Care Markets Work: Competition Policy for Health Care,* 16–17 (Apr. 2017), *available at http://heinz.cmu.edu/news/news-detail/index.aspx?nid=3930;* Diego A. Martinez et al., *A Strategic Gaming Model For Health Information Exchange Markets,* Health Care Mgmt. Science (Sept. 2016). (''[S]ome healthcare provider entities may be interfering with HIE across disparate and unaffiliated providers to gain market advantage.'') Niam Yaraghi, *A Sustainable Business Model for Health Information Exchange Platforms: The Solution to Interoperability in Healthcare IT* (2015), *available at http://www.brookings.edu/research/papers/2015/01/30-sustainable-business-model-health-information-exchange-yaraghi;* Thomas C. Tsai & Ashish K. Jha, *Hospital Consolidation, Competition, and Quality: Is Bigger Necessarily Better?,* 312 J. AM. MED. ASSOC. 29, 29 (2014).

information blocking in broad terms, while working to deter the entire spectrum of practices that unnecessarily impede the flow of EHI or its use to improve health and the delivery of care. The information blocking provision applies to the conduct of health care providers, and to health IT developers of certified health IT, exchanges, and networks, and seeks to deter it with substantial penalties, including civil money penalties, and disincentives for violations. Additionally, developers of health IT certified under the Program are prohibited from information blocking under 3001(c)(5)(D)(i) of the PHSA. To promote effective enforcement, the information blocking provision empowers the HHS Office of Inspector General (OIG) to investigate claims of information blocking and provides referral processes to facilitate coordination with other relevant agencies, including ONC, the HHS Office for Civil Rights (OCR), and the Federal Trade Commission (FTC). The information blocking provision also provides for a complaint process and corresponding confidentiality protections to encourage and facilitate the reporting of information blocking. Enforcement of the information blocking provision is buttressed by section 3001(c)(5)(D)(i) and (vi) of the PHSA, which prohibits information blocking by developers of certified health IT as a Condition and Maintenance of Certification requirement under the Program and requires them to attest that they have not engaged in such practices.

2. Policy Considerations and Approach to the Information Blocking Provision

To ensure that individuals and entities that engage in information blocking are held accountable, the information blocking provision encompasses a relatively broad range of potential practices. For example, it is possible that some activities that are innocuous, or even beneficial, could technically implicate the information blocking provision. Given the possibility of these practices, Congress authorized the Secretary to identify reasonable and necessary activities that do not constitute information blocking (see section 3022(a)(3) of the PHSA) (in this proposed rule, we refer to such reasonable and necessary activities identified by the Secretary as ''exceptions'' to the information blocking provision). The information blocking provision also excludes from the definition of information blocking practices that are required by law (section 3022(a)(1) of the PHSA) and clarifies certain other practices that would not be penalized (sections 3022(a)(6) and (7) of the PHSA).

In considering potential exceptions to the information blocking provision, we must balance a number of policy and practical considerations. To minimize compliance and other burdens for stakeholders, we seek to promote policies that are clear, predictable, and administrable. In addition, we seek to implement the information blocking provision in a way that is sensitive to legitimate practical challenges that may prevent access, exchange, or use of EHI in certain situations. We must also accommodate practices that, while they may inhibit access, exchange, or use of EHI, are reasonable and necessary to advance other compelling policy interests, such as preventing harm to patients and others, promoting the privacy and security of EHI, and promoting competition and consumer welfare.

At the same time, while pursuing these objectives, we must adhere to Congress's plainly expressed intent to provide a comprehensive response to the information blocking problem. Information blocking can occur through a variety of business, technical, and organizational practices that can be difficult to detect and that are constantly changing as technology and industry conditions evolve. The statute responds to these challenges by defining information blocking broadly and in a manner that allows for careful consideration of relevant facts and circumstances in individual cases.

Accordingly, we propose to establish certain defined exceptions to the information blocking provision. These exceptions would be subject to strict conditions that balance the considerations described above. Based on those considerations, in developing the proposed exceptions, we applied three overarching policy criteria. First, each exception would be limited to certain activities that are both reasonable and necessary to advance the aims of the information blocking provision. These reasonable and necessary activities include: Promoting public confidence in the health IT infrastructure by supporting the privacy and security of EHI, and protecting patient safety; and promoting competition and innovation in health IT and its use to provide health care services to consumers. Second, we believe that each exception addresses a significant risk that regulated individuals and entities will not engage in these reasonable and necessary activities because of uncertainty regarding the breadth or applicability of the information blocking provision. Third, and last, each exception is intended to be tailored, through appropriate conditions, so that it is limited to the reasonable and necessary activities that it is designed to protect and does not extend protection to other activities or practices that could raise information blocking concerns.

We discuss these policy considerations in more detail in the context of each of the exceptions proposed in section VIII.D of this preamble.

C. Relevant Statutory Terms and Provisions

In this section of the preamble, we discuss how we propose to interpret certain aspects of the information blocking provision that we believe are ambiguous, incomplete, or that provide the Secretary with discretion. We propose to define or interpret certain terms or concepts that are present in the statute and, in a few instances, to establish new regulatory terms or definitions that we believe are necessary to implement the Secretary's authority under section 3022(a)(3) to identify reasonable and necessary activities that do not constitute information blocking. Our goal in interpreting the statute and defining relevant terms is to provide greater clarity concerning the types of practices that could implicate the information blocking provision and, relatedly, to more effectively communicate the applicability and scope of the proposed exceptions outlined in this proposed rule. We believe that these proposals will provide a more meaningful opportunity for the public to comment on the proposed exceptions and our overall approach to interpreting and administering the information blocking provision. Additionally, we believe additional interpretive clarity will assist regulated actors to comply with the requirements of the information blocking provision.

1. ''Required by Law''

With regard to the statute's exclusion of practices that are ''required by law'' from the definition of information blocking, we emphasize that ''required by law'' refers specifically to interferences with access, exchange, or use of EHI that are explicitly required by state or federal law. By carving out practices that are ''required by law,'' the statute acknowledged that there are state and federal laws that advance important policy interests and objectives by restricting access, exchange, and use of their EHI, and that practices that follow such laws should not be considered information blocking.

We note that for the purpose of developing an exception for reasonable and necessary privacy-protective practices, we have distinguished between interferences that are ''required by law'' and those engaged in pursuant to a privacy law, but which are not ''required by law.'' The former does not fall within the definition of information blocking, but the latter may implicate the information blocking provision and an exception may be necessary. For a detailed discussion of this topic, please see section VIII.D.2 of this preamble.

2. Health Care Providers, Health IT Developers, Exchanges, and Networks

Section 3022(a)(1) of the PHSA, in defining information blocking, refers to four classes of individuals and entities that may engage in information blocking and which include: Health care providers, health IT developers of certified health IT, networks, and exchanges. We propose to adopt definitions of these terms to provide clarity regarding the types of individuals and entities to whom the information blocking provision applies. We note that, for convenience and to avoid repetition in this preamble, we typically refer to these individuals and entities covered by the information blocking provision as ''actors'' unless it is relevant or useful to refer to the specific type of individual or entity. That is, when the term ''actor'' appears in this preamble, it means an individual or entity that is a health care provider, health IT developer, exchange, or network. For the same reasons, we propose to define ''actor'' in § 171.102.

a. Health Care Providers

The term ''health care provider'' is defined in section 3000(3) of the PHSA. We propose to adopt this definition for purposes of section 3022 of the PHSA when defining ''health care provider'' in § 171.102. We note that this definition is different from the definition of ''health care provider'' under the HIPAA Privacy and Security Rules. We are considering adjusting the information blocking definition of ''health care provider'' to cover all individuals and entities covered by the HIPAA ''health care provider'' definition. We seek comment on whether this approach would be justified, and commenters are encouraged to specify reasons why doing so might be necessary to ensure that the information blocking provision applies to all health care providers that might engage in information blocking.

b. Health IT Developers of Certified Health IT

Section 3022(a)(1)(B) of the PHSA defines information blocking, in part, by reference to the conduct of ''health information technology developers.'' Because title XXX of the PHSA does not define ''health information technology developer,'' we interpret section 3022(a)(1)(B) in light of the specific authority provided to OIG in section 3022(b)(1)(A) and (b)(2). Section 3022(b)(2) discusses developers, networks, and exchanges in terms of an ''individual or entity,'' specifically cross-referencing section 3022(b)(1)(A). Sections 3002(b)(1) and (b)(1)(A) state, in relevant part, that the OIG may investigate information blocking claims regarding a health information technology developer of certified health information technology or other entity offering certified health information technology. Together, these sections make clear that the information blocking provisions and OIG's authority extend to individuals *or* entities that develop *or* offer certified health IT. That the individual or entity must develop or offer *certified* health IT is further supported by section 3022(a)(7) of the PHSA—which refers to developers' responsibilities to meet the requirements of certification—and section 4002 of the Cures Act—which identifies information blocking as a Condition of Certification.

Notwithstanding this, the Cures Act does not prescribe that conduct that may implicate the information blocking provisions be limited to practices related to *only* certified health IT. Rather, the information blocking provisions would be implicated by any practice engaged in by an individual or entity that develops or offers certified health IT that is likely to interfere with the access, exchange, or use of EHI, including practices associated with *any* of the developer or offeror's health IT products that have *not* been certified under the Program. This interpretation is based primarily on section 3022(b)(1) of the PHSA. If Congress had intended that the enforcement of the information blocking provisions were limited to practices connected to certified health IT, we believe the Cures Act would have included language that tied enforcement to the operation or performance of a product certified under the Program. Rather, the description of the practices that OIG can investigate in section 3022(b)(1)(A)(ii) of the PHSA are not tied to the certification status of the health IT at issue, omitting any express reference to a health IT developer's practice needing to be related to ''certified health information technology.'' That the scope of the information blocking provision should not be limited to practices that involve only certified health IT is further evidenced by no such limitation applying to health care providers, health information exchanges (HIEs), and health information networks (HINs) as listed in sections 3022(b)(1) of the PHSA.

Additionally, the ''practice described'' in section 3022(a)(2) of the PHSA refers to ''certified health information technologies'' when illustrating practices that restrict authorized access, exchange, or use of EHI under applicable state or federal laws (section 3022(a)(2)(A) of the PHSA), but omits any reference to certification when describing ''health information technology'' in the practices described in sections 3022(a)(2)(B) and (C) of the PHSA. Importantly, sections 3022(a)(2)(B) and (C) of the PHSA address practices that are particularly relevant to health IT developers and offerors, although they could be engaged in by other types of actors. We interpret this drafting as a deliberate decision not to link the information blocking provisions with only the performance or use of certified health IT.

Finally, we note that the Cures Act does not impose a temporal nexus that would require that information blocking be carried out at a time when an individual or entity had health IT certified under the Program. Ostensibly, then, once an individual or entity has health IT certified, or otherwise maintains the certification of health IT, the individual or entity becomes forever subject to the information blocking provision. We do not believe that, understood in context, the Cures Act supports such a broad interpretation. Noting the above discussion concerning OIG's scope of authority under section 3022(b)(1)(A) and (b)(2) of the PHSA, we believe that to make developers and offerors of certified health IT subject to the information blocking provision in perpetuity would be inconsistent with the voluntary nature of the Program. However, we also believe that the Cures Act does not provide any basis for interpreting the information blocking provision so narrowly that a developer or offeror of certified health IT could escape penalty as a consequence of having its certification terminated or by withdrawing all of its extant certifications.

We consider that in the circumstances where a health IT developer has its certification terminated, or withdraws its certification, such that it no longer has any health IT certified under the

Program, it should nonetheless be subject to penalties for information blocking engaged in during the time that it did have health IT certified under the Program. Accordingly, we propose to adopt a definition of ''heath information technology (IT) developer of certified health IT'' for the purposes of interpretation and enforcement of the information blocking provisions, including those regulatory provisions proposed under Title 45, part 171, of the Code of Federal Regulations, that would capture such developers or offerors. We propose, in § 171.102, that ''health IT developer of certified health IT'' means an individual or entity that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which had, at the time it engaged in a practice that is the subject of an information blocking claim, health IT (one or more) certified under the Program. To note, we propose that the term ''information blocking claim'' within this definition should be read broadly to encompass any statement of information blocking or potential information blocking. ''Claims'' of information blocking within this definition would not be limited, in any way, to a specific form, format, or submission approach or process.

We are also considering additional approaches to help ensure that developers and offerors of certified health IT remain subject to the information blocking provision for an appropriate period of time after leaving the Program. The rationale for this approach would be that a developer or offeror of certified health IT should be subject to penalties if, following the termination or withdrawal of certification, it refused to provide its customers with access to the EHI stored in the decertified health IT, provided that such interference was not required by law and did not qualify for one of the information blocking exceptions. Adopting this broader approach would help avoid the risk that a developer would be able to engage in the practices described in section 3022(a)(2) of the PHSA in respect to EHI that was collected on behalf of a health care provider when that health care provider would reasonably expect that the information blocking provision would protect against unreasonable and unnecessary interferences with that EHI. If the information blocking provision did not extend to capture such conduct, the protection afforded by the information blocking provision could become illusory, and providers would need to consider securing contractual rights to prevent interference, which we are aware they typically have great difficulty doing.[104]

One way that this could be achieved would be to define ''health IT developer of certified health IT'' as including developers and offerors of certified health IT that continue to store EHI that was previously stored in health IT certified in the Program. Alternatively, we are considering whether developers and offerors of certified health IT should remain subject to the information blocking provision for an appropriate period of time after leaving the Program. Namely, that the information blocking provision should apply for a specific time period, say one year, after the developer or offeror no longer has any health IT certified in the Program. This second approach has the attraction of providing a more certain basis for understanding which developers are subject to the information blocking provision. However, it also potentially captures developers and offerors who have fully removed themselves from the Program and, for example, no longer exercise control over EHI that was stored in their certified health IT.

We seek comment on which of these two models best achieves our policy goal of ensuring that health IT developers of certified health IT will face consequences under the information blocking provision if they engage in information blocking in connection with EHI that was stored or controlled by the developer or offeror whilst they were participating in the program. Commenters are also encouraged to identify alternative models and approaches for identifying when a developer or offeror should, and should no longer, be subject to the information blocking provision.

We note that a developer or offeror of a single health IT product that has had its certification suspended would be considered to *have* certified health IT for the purpose of the definition. We also note that we interpret the requirement that the health IT developer of certified health IT ''exercise control'' over EHI broadly. A developer would not necessarily need to have access to the EHI in order to exercise control. For example, a developer that implemented a ''kill-switch'' for a decertified software product that was locally hosted by a health care provider, preventing that provider from accessing its records, would be exercising control over the EHI for the purpose of this definition.

We clarify that we interpret ''individual or entity that develops the certified health IT'' as the individual or entity that is legally responsible for the certification status of the health IT, which would be the individual or entity that entered into a binding agreement that resulted in the certification status of the health IT under the Program or, if such rights are transferred, the individual or entity that holds the rights to the certified health IT. We also clarify that an ''individual or entity that offers certified health IT'' would include an individual or entity that under any arrangement makes certified health IT available for purchase or license. We seek comment on both of our interpretations. More specifically, we seek comment on whether there are particular types of arrangements under which certified health IT is ''offered'' in which the offeror should not be considered a ''health IT developer of certified health IT'' for the purposes of the information blocking provisions.

We also clarify that the proposed definition of ''health IT developer of certified health IT'' and our interpretation of the use of ''health information technology developer'' applies to Part 171 only and does not apply to the implementation of any other section of the PHSA or the Cures Act, including section 4005(c)(1) of the Cures Act.

We clarify that API Technology Suppliers, as described in section VII.4 of this preamble and defined in § 170.102, would be considered health IT developers of certified health IT subject to the conditions described above.

Last, we clarify that a ''self-developer'' of certified health IT, as the term has been used in the ONC Health IT Certification Program (Program) and described in this rulemaking (section VII.D.7) and previous rulemaking,[105] would be treated as a health care provider for the purposes of information blocking. This is because of our description of a self-developer for Program purposes [106] would essentially mean that such developers would not be supplying or offering their certified health IT to other entities. To be clear, self-developers would still be subject to the proposed Conditions and

[104] *See* ONC, *EHR Contracts Untangled Selecting Wisely, Negotiating Terms, And Understanding The Fine Print, https://www.healthit.gov/sites/default/files/EHR_Contracts_Untangled.pdf* (September 2016).

[105] The final rule establishing ONC's Permanent Certification Program, ''Establishment of the Permanent Certification for Health Information'' (76 FR 1261), addresses self-developers.

[106] The language in the final rule describes the concept of ''self-developed'' as referring to a complete EHR or EHR Module designed, created, or modified by an entity that assumed the total costs for testing and certification and that will be the primary user of the health IT (76 FR 1300).

Maintenance of Certification requirements because they have health IT certified under the Program (*see also* section VII.D.7). We welcome comments on our determination regarding ''self-developers'' for information blocking purposes and whether there are other factors we should consider in how we treat ''self-developers'' of certified health IT for the purposes of information blocking.

We also seek comment generally on the definition proposed for ''health IT developer of certified health IT.''

c. Networks and Exchanges

The terms ''network'' and ''exchange'' are not defined in the information blocking provision or in any other relevant statutory provisions. We propose to define these terms so that these individuals and entities that are covered by the information blocking provision understand that they must comply with its provisions. In accordance with the meaning and intent of the information blocking provision, we believe it is necessary to define these terms in a way that does not assume the application or use of certain technologies and is flexible enough to apply to the full range and diversity of exchanges and networks that exist today and may arise in the future. We note that in the past few years alone many new types of exchanges and networks that transmit EHI have emerged, and we expect this trend to accelerate with continued advancements in technology and renewed efforts to advance trusted exchange among networks and other entities under the trusted exchange framework and common agreement provided for by section 4003(b) of the Cures Act.

In considering the most appropriate way to define these terms, we examined how they are used throughout the Cures Act and the HITECH Act. Additionally, we considered dictionary and industry definitions of ''network'' and ''exchange.'' While these terms have varied usage and meaning in different industry contexts, certain concepts are common and have been incorporated into the proposed definitions below.

i. Health Information Network

We propose a functional definition of ''health information network'' (HIN) that focuses on the role of these actors in the health information ecosystem. We believe the defining attribute of a HIN is that it enables, facilitates, or controls the movement of information between or among different individuals or entities that are unaffiliated. For this purpose, we propose that two parties are affiliated if one has the power to control the other, or if both parties are under the common control or ownership of a common owner. We note that a significant implication of this definition is that a health care provider or other entity that enables, facilitates, or controls the movement of EHI within its own organization, or between or among its affiliated entities, is not a HIN in connection with that movement of information for the purposes of this proposed rule.

More affirmatively, we propose that an actor could be considered a HIN if it performs any or any combination of the following activities. First, the actor would be a HIN if it were to determine, oversee, administer, control, or substantially influence policies or agreements that define the business, operational, technical, or other conditions or requirements that enable or facilitate the access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities. Second, an actor would be a HIN if it were to provide, manage, control, or substantially influence any technology or service that enables or facilitates the access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities.

Typically, a HIN will influence the sharing of EHI between many unaffiliated individuals or entities. However, we do not propose to establish any minimum number of parties or ''nodes'' beyond the requirement that there be some actual or contemplated access, exchange, or use of information between or among at least two unaffiliated individuals or entities that is enabled, facilitated, or controlled by the HIN. We believe such a limitation would be artificial and would not capture the full range of entities that should be considered networks under the information blocking provision. To be clear, any individual or entity that enables, facilitates, or controls the access, exchange, or use of EHI between or among only itself and another unaffiliated individual or entity would not be considered a HIN in connection with the movement of that EHI (although that movement of EHI may still be regulated under the information blocking provision on the basis that the individual or entity is a health care provider or health IT developer of certified health IT). To be a HIN, the individual or entity would need to be enabling, facilitating, or controlling the access, exchange, or use of EHI between or among two or more *other* individuals or entities that were not affiliated with it.

To illustrate how the proposed definition would operate, we note the following examples. An entity is established within a state for the purpose of improving the movement of EHI between the health care providers operating in that state. The entity identifies standards relating to security and offers terms and conditions to be entered into by health care providers wishing to participate in the network. The entity offering (and then overseeing and administering) the terms and conditions for participation in the network would be considered a HIN for the purpose of the information blocking provision. We note that there is no need for a separate entity to be created in order that an entity be considered a HIN. For instance, a health system that administers business and operational agreements for facilitating the exchange of EHI that are adhered to by unaffiliated family practices and specialist clinicians in order to streamline referrals between those practices and specialists would likely be considered a HIN.

We note that the proposed definition would also encompass an individual or entity that does not directly enable, facilitate, or control the movement of information, but nonetheless exercises control or substantial influence over the policies, technology, or services of a network. In particular, there may be an individual or entity that relies on another entity—such as an entity specifically created for the purpose of managing a network—for policies and technology, but nevertheless dictates the movement of EHI over that network. For example, a large health care provider may decide to lead an effort to establish a network that facilitates the movement of EHI between a group of smaller health care providers (as well as the large health care provider) and through the technology of health IT developers. To achieve this outcome, the large health care provider, together with some of the participants, creates a new entity that administers the network's policies and technology. In this scenario, the large health care provider would come within the functional definition of a HIN and could be held accountable for the conduct of the network if the large health care provider used its control or substantial influence over the new entity—either in a legal sense, such as via its control over the governance or management of the entity, or in a less formal sense, such as if the large health care provider prescribed a policy to be adopted—to interfere with the access, exchange, or use of EHI. We note that the large health care provider in this example would be treated as a health care provider when utilizing the

network to move EHI via the network's policies, technology, or services, but would be considered a HIN in connection with the practices of the network over which the large health care provider exercises control or substantial influence.

We seek comment on the proposed definition of a HIN. In particular, we request comment on whether the proposed definition is broad enough (or too broad) to cover the full range of individuals and entities that could be considered health information networks within the meaning of the information blocking provision. Additionally, we specifically request comment on whether the proposed definition would effectuate our policy goal of defining this term in a way that does not assume particular technologies or arrangements and is flexible enough to accommodate changes in these and other conditions.

ii. Health Information Exchange

We propose to define a ''health information exchange'' (HIE) as an individual or entity that enables access, exchange, or use of EHI primarily between or among a particular class of individuals or entities or for a limited set of purposes. Our research and experience in working with exchanges drove the proposed definition of this term. HIEs include but are not limited to regional health information organizations (RHIOs), state health information exchanges (state HIEs), and other types of organizations, entities, or arrangements that enable EHI to be accessed, exchanged, or used between or among particular types of parties or for particular purposes. For example, an HIE might facilitate or enable the access, exchange, or use of EHI exclusively within a regional area (such as a RHIO), or for a limited scope of participants and purposes (such as a clinical data registry or an exchange established by a hospital-physician organization to facilitate Admission, Discharge, and Transfer (ADT) alerting). We note that HIEs may be established under federal or state laws or regulations but may also be established for specific health care or business purposes or use cases. Additionally, we note that if an HIE facilitates the access, exchange, or use of EHI for more than a narrowly defined set of purposes, then it may be both an HIE and a HIN.

We seek comment on this proposed definition of an HIE. Again, we encourage commenters to consider whether this proposed definition is broad enough (or too broad) to cover the full range of individuals and entities that could be considered exchanges within the meaning of the information blocking provision, and whether the proposed definition is sufficiently flexible to accommodate changing technological and other conditions.

3. Electronic Health Information

The definition of information blocking applies to *electronic* health information (EHI) (section 3022(a)(1) of the PHSA). While section 3000(4) of the PHSA by reference to section 1171(4) of the Social Security Act defines ''health information,'' EHI is not specifically defined in the Cures Act, HITECH Act, or other relevant statutes. We propose to define EHI to mean:

(i) Electronic protected health information; and

(ii) any other information that—

- is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103;
- identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual; and
- relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

This definition of EHI includes, but is not limited to, electronic protected health information and health information that is created or received by a health care provider and those operating on their behalf; health plan; health care clearinghouse; public health authority; employer; life insurer; school; or university. In addition, we clarify that under our proposed definition, EHI includes, but is not limited to, electronic protected health information (ePHI) as defined in 45 CFR 160.103. In particular, unlike ePHI and health information, EHI is not limited to information that is created or received by a health care provider, health plan, health care clearinghouse, public health authority, employer, life insurer, school, or university. EHI may be provided, directly from an individual, or from technology that the individual has elected to use, to an actor covered by the information blocking provisions. We propose that EHI does not include health information that is de-identified consistent with the requirements of 45 CFR 164.514(b). We generally request comment on this proposed definition as well as on whether the exclusion of health information that is de-identified is consistent with the requirements of 45 CFR 164.514(b).

To be clear, this definition provides for an expansive set of EHI, which could include information on an individual's health insurance eligibility and benefits, billing for health care services, and payment information for services to be provided or already provided, which may include price information.

Price Information

The fragmented and complex nature of pricing within the health care system has decreased the efficiency of the health care system and has had negative impacts on patients, health care providers, health systems, plans, plan sponsors and other key health care stakeholders. Patients and plan sponsors have trouble anticipating or planning for costs, are not sure how they can lower their costs, are not able to compare costs, and have no practical way to measure the quality of the care or coverage they receive relative to the price they pay. Pricing information continues to grow in importance with the increase of high deductible health plans and surprise billing, which have resulted in an increase in out-of-pocket health care spending. Transparency in the price and cost of health care would help address the concerns outlined above by empowering patients to make informed health care decisions. Further, the availability of price information could help increase competition that is based on the quality and value of the services patients receive. Consistent with its statutory authority, the Department is considering subsequent rulemaking to expand access to price information for the public, prospective patients, plan sponsors, and health care providers.

Increased consumer demand, aligned incentives, more accessible and digestible information, and the evolution of price transparency tools are critical components to moving to a health care system that pays for value. However, the complex and decentralized nature of how price information is created, structured, formatted, and stored presents many challenges to achieving price transparency. To this point, pricing within health care demands a market-based approach whereby, for example, platforms are created that utilize raw data to provide consumers with digestible price information through their preferred medium.

ONC has a unique role in setting the stage for such future actions by establishing the framework to prevent the blocking of price information. Given that price information impacts the ability of patients to shop for and make decisions about their care, we seek comment on the parameters and implications of including price information within the scope of EHI for purposes of information blocking. In

addition, the overall Department seeks comment on the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care.

- Should prices that are included in EHI:
  - Reflect the amount to be charged to and paid for by the patient's health plan (if the patient is insured) and the amount to be charged to and collected from the patient (as permitted by the provider's agreement with the patient's health plan), including for drugs or medical devices;
  - Include various pricing information such as charge master price, negotiated prices, pricing based on CPT codes or DRGs, bundled prices, and price to payer;
  - Be reasonably available in advance and at the point of sale;
  - Reflect all out-of-pocket costs such as deductibles, copayments and coinsurance (for insured patients); and/or
  - Include a reference price as a comparison tool such as the Medicare rate and, if so, what is the most meaningful reference?
- For the purpose of informing referrals for additional care and prescriptions, should future rulemaking by the Department require health IT developers to include in their platforms a mechanism for patients to see price information, and for health care providers to have access to price information, tailored to an individual patient, integrated into the practice or clinical workflow through APIs?
- To the extent that patients have a right to price information within a reasonable time in advance of care, how would such reasonableness be defined for:
  - Scheduled care, including how far in advance should such pricing be available for patients still shopping for care, in addition to those who have already scheduled care;
  - Emergency care, including how and when transparent prices should be disclosed to patients and what sort of exceptions might be appropriate, such as for patients in need of immediate stabilization;
  - Ambulance services, including air ambulance services; and
  - Unscheduled inpatient care, such as admissions subsequent to an emergency visit?
- How would price information vary based on the type of health insurance and/or payment structure being utilized, and what, if any, challenges would such variation create to identifying the price information that should be made available for access, exchange, or use?
- Are there electronic mechanisms/processes available for providing price information to patients who are not registered (*i.e.,* not in the provider system) when they try to get price information?
- Should price information be made available on public websites so that patients can shop for care without having to contact individual providers, and if so, who should be responsible for posting such information? Additionally, how would the public posting of pricing information through API technology help advance market competition and the ability of patients to shop for care?
- If price information that includes a provider's negotiated rates for all plans and the rates for the uninsured were to be required to be posted on a public website, is there technology currently available or that could be easily developed to translate that data into a useful format for individuals? Are there existing standards and code sets that would facilitate such transmission and translation? To the extent that some data standards are lacking in this regard, could developers make use of unstandardized data?
- What technical standards currently exist or may be needed to represent price information electronically for purposes of access, exchange, and use?
- Are there technical impediments experienced by stakeholders regarding price information flowing electronically?
- Would updates to the CMS-managed HIPAA transactions standards and code sets be necessary to address the movement of price information in a standardized way?
- How can price transparency be achieved for care delivered through value based arrangements, including at accountable care organizations, demonstrations and other risk-sharing arrangements?
- What future requirements should the Department consider regarding the inclusion of price information in a patient's EHI, particularly as it relates to the amount paid to a health care provider by a patient (or on behalf of a patient) as well as payment calculations for the future provision of health care to such patient?
- If price information is included in EHI, could that information be useful in subsequent rulemaking that the Department may consider in order to reduce or prevent surprise medical billing, such as requirements relating to:
  - The provision of a single bill that includes all health care providers involved in a health care service, including their network status;
  - The provision of a binding quote reasonably in advance of scheduled care (that is, non-emergent care) or some subset of scheduled care, such as for the most ''shoppable'' services;
  - Ensuring that all health care providers in an in-network facility charge the in-network rate; and
  - Notification of billing policies such as timely invoice dates for all providers and facilities, notwithstanding network status, due date for invoice payments by the prospective patient's payers and out-of-pocket obligations, date when unpaid balances are referred for collections, and appeals rights and procedures for patients wishing to contest an invoice?

4. Interests Promoted by the Information Blocking Provision

a. Access, Exchange, and Use of EHI

The information blocking provision promotes the ability to *access, exchange, and use* EHI, consistent with the requirements of applicable law. We interpret the terms ''access,'' ''exchange,'' and ''use'' broadly, consistent with their generally understood meaning in the health IT industry and their function and context in the information blocking provision.

The concepts of access, exchange, and use are closely related: EHI cannot be used unless it can be accessed, and this often requires that the EHI be exchanged among different individuals or entities and through various technological means. Moreover, the technological and other means necessary to facilitate appropriate access and exchange of EHI vary significantly depending on the purpose for which the information will be used. For example, the technologies and services that support a payer's access to EHI to assess clinical value will likely differ from those that support a patient's access to EHI via a smartphone app. That is, to deter information blocking in these and many other potential uses of EHI—and, by extension, the many and diverse means of access and exchange that support such uses.

This is consistent with the way these terms are employed in the information blocking provision and in other relevant statutory provisions. For example, section 3022(a)(2) of the PHSA contemplates a broad range of purposes for which EHI may be accessed, exchanged, and used—from treatment, care delivery, and other permitted purposes, to exporting complete information sets and transitioning between health IT systems, to supporting innovations and advancements in health information access, exchange, and use. Separately,

the Cures Act and the HITECH Act contemplate many different purposes for and means of accessing, exchanging, and using EHI, which include, but are not limited to, quality improvement, guiding medical decisions at the time and place of care, reducing medical errors and health disparities, delivering patient-centered care, and supporting public health and clinical research activities.[107]

In addition to these statutory provisions, we have considered how the terms access, exchange, and use have been defined or used in existing regulations and other relevant health IT industry contexts. While those definitions have specialized meanings and are not controlling here, they are instructive insofar as they illustrate the breadth with which these terms have been understood in other contexts. For example, the HIPAA Privacy Rule defines an individual's right of access to include the right to have a copy of all or part of their PHI transmitted directly to them or any person or entity he or she designates, in any form and format (including electronically) that the individual requests and that the covered entity holding the information can readily produce (45 CFR 164.524). In a different context, the HIPAA Security Rule defines ''access'' as the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource (45 CFR 164.304). The HIPAA Rules also define the term ''use,'' which includes the sharing, employment, application, utilization, examination, or analysis of individually identifiable health information within an entity that maintains the information (45 CFR 160.103).

As the examples and discussion above demonstrate, the concepts of access, exchange, and use are used in a variety of contexts to refer to a broad spectrum of activities. We believe that the types of access, exchange, and use described above would be promoted under the information blocking provision, as would other types of access, exchange, or use not specifically contemplated in these or other regulations. Further, we note that the information blocking provision would also extend to innovations and advancements in health information access, exchange, and use that may occur in the future (see section 3022(a)(2) of the PHSA).

Consistent with the above, and to convey the full breadth of activities that may implicate the information blocking provision, we propose definitions of access, exchange, and use in § 171.102. We emphasize the interrelated nature of the definitions. For example, the definition of ''use'' includes the ability to read, write, modify, manipulate, or apply EHI to accomplish a desired outcome or to achieve a desired purpose, while ''access'' is defined as the ability or means necessary to make EHI available for *use.* As such, interference with ''access'' would include, for example, an interference that prevented a health care provider from writing EHI to its health IT or from modifying EHI stored in health IT, whether by the provider itself or by, or via, a third-party app. We encourage comment on these definitions. In particular, commenters may wish to consider whether these definitions are broad enough to cover all of the potential purposes for which EHI may be needed and ways in which it could conceivably be used, now and in the future.

b. Interoperability Elements

In this proposed rule, we use the term ''interoperability element'' to refer to any means by which EHI can be accessed, exchanged, or used. We clarify that the means of accessing, exchanging, and using EHI are not limited to functional elements and technical information but also encompass technologies, services, policies, and other conditions [108] necessary to support the many potential uses of EHI as described above. Because of the evolving nature of technology and the diversity of privacy laws and regulations, institutional arrangements, and policies that govern the sharing of EHI, we will not provide an exhaustive list of interoperability elements. However, we believe that it is useful to define this term, both because of its importance for analyzing the likelihood of interference under the information blocking provision, and because some of the proposed exceptions to the provision contain conditions concerning the availability and provision of interoperability elements. Therefore, we propose to define ''interoperability element'' in § 171.102. As noted, our intent is to capture all of the potential means by which EHI may be accessed, exchanged, or used for any relevant purposes; both now and as technology and other conditions evolve. We seek comment on whether the proposed definition realizes that intent and, if not, any changes we should consider.

5. Practices That May Implicate the Information Blocking Provision

To meet the definition of information blocking, a practice must be *likely to interfere with, prevent, or materially discourage* access, exchange, or use of EHI. In this section and elsewhere in this preamble, we discuss various types of hypothetical practices that *could* implicate the provision. We do this to illustrate the scope of the information blocking provision and to explain our interpretation of various statutory concepts. However, we stress that the types of practices discussed in this preamble are illustrative, not exhaustive, and that many other types of practices could also implicate the provision. Nor does the fact that we have not identified or discussed a particular type of practice imply that it is less serious than those that are discussed in this preamble. Indeed, because information blocking may take many forms, it is not possible—and we do not attempt—to anticipate or catalog the many potential types of practices that may raise information blocking concerns.

We emphasize that any analysis of information blocking necessarily requires a careful consideration of the individual facts and circumstances, including whether the practice was required by law, whether the actor had the requisite statutory knowledge, and whether an exception applies. When we state that a practice would implicate the provision or *could* violate the provision, we are expressing a conclusion that the type of practice is one that would be likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI, and that further analysis of these and other statutory elements would therefore be warranted to determine whether a violation has occurred. We highlight this distinction because to *implicate* the information blocking provision is *not* necessarily to *violate* it, and that each case will turn on its own unique facts. For example, a practice that seemingly meets the statutory definition of information blocking would not be information blocking if it was required by law, if one or more elements of the definition were not met, or if was covered by one of the proposed exceptions.

We propose in section VIII.D of this preamble to establish seven exceptions to the information blocking provision for certain reasonable and necessary activities. If an actor can establish that an exception applies to each practice for which a claim of information blocking

[107] *See* section 3001(b) of the PHSA; *see also* section 3009(a)(3) of the PHSA (enumerating reporting criteria relating to access, exchange, and use of EHI for a broad and diverse range of purposes).

[108] *See* ONC, *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* at x–xi, *https://www.healthit.gov/topic/interoperability/interoperability-roadmap* (Oct. 2015) [hereinafter ''Interoperability Roadmap'']

has been made, including that the actor satisfied all applicable conditions of the exception at all relevant times, then the practice would not constitute information blocking.

Based on early discussions with stakeholders during the development of this proposed rule, we are aware that the generality with which the information blocking provision describes practices that are likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI may leave some uncertainty as to the scope of the information blocking provision and the types of practices that will implicate enforcement by ONC and/or OIG. To provide additional clarity on this point, we elaborate our understanding of these important statutory concepts below.

a. Prevention, Material Discouragement, and Other Interference

The information blocking provision and its enforcement subsection do not define the terms ''interfere with,'' ''prevent,'' and ''materially discourage,'' and use these terms collectively and without differentiation. Based on our interpretation of the information blocking provision and the ordinary meanings of these terms in the context of EHI, we do not believe they are mutually exclusive, but that prevention and material discouragement are best understood as types of interference, and that use of these terms in the statute to define information blocking illustrates the desire to reach all practices that an actor knows, or should know, are likely to prevent, materially discourage, or otherwise interfere with the access, exchange, or use of EHI. Consistent with this understanding, in this preamble to the proposed rule, we use the terms ''interfere with'' and ''interference'' as inclusive of prevention, material discouragement, and other forms of interference that implicate the information blocking provision.

We believe that interference could take many forms. In addition to the prevention or material discouragement of access, exchange, or use, we propose that interference could include practices that increase the cost, complexity, or other burden associated with accessing, exchanging, or using EHI. Additionally, interference could include practices that limit the utility, efficacy, or value of EHI that is accessed, exchanged, or used, such as by diminishing the integrity, quality, completeness, or timeliness of the data. We refer readers to section VIII.C.5.c of this preamble below for a discussion of these and other potential practices that could interfere with access, exchange, or use and thereby implicate the information blocking provision.

Relatedly, to avoid potential ambiguity and clearly communicate the full range of potential practices that could implicate the information blocking provision, we propose to codify a definition of ''interfere with'' in § 171.102, consistent with our interpretation set forth above.

b. Likelihood of Interference

The information blocking provision is preventative in nature. That is, the information blocking provision proscribes practices that are *likely* to interfere with (including preventing or materially discouraging) access, exchange, or use of EHI—whether or not such harm actually materializes. By including both the likely and the actual effects of a practice, the information blocking provision encourages individuals and entities to avoid engaging in practices that undermine interoperability, and to proactively promote access, exchange, and use of EHI.

We believe that a practice would satisfy the information blocking provision's ''likelihood'' requirement if, under the circumstances, there is a reasonably foreseeable risk that the practice will interfere with access, exchange, or use of EHI. For example, where an actor refuses to share EHI or to provide access to certain interoperability elements, it is reasonably foreseeable that such actions will interfere with access, exchange, or use of EHI. As another example, it is reasonably foreseeable that a health care provider may need to access information recorded in a patient's electronic record that could be relevant to the treatment of that patient. For this reason, a policy or practice that limits timely access to such information in an appropriate electronic format creates a reasonably foreseeable likelihood of interfering with the use of the information for these treatment purposes.

Whether the risk of interference is reasonably foreseeable will depend on the particular facts and circumstances attending the practice or practices at issue. Because of the number and diversity of potential practices, and the fact that different practices will present varying risks of interfering with access, exchange, or use of EHI, we do not attempt to anticipate all of the potential ways in which the information blocking provision could be implicated. Nevertheless, to assist with compliance, we clarify certain circumstances in which, based on our experience, a practice will almost always be likely to interfere with access, exchange, or use of EHI. We caution that these situations are not exhaustive and that other circumstances may also give rise to a very high likelihood of interference under the information blocking provision. In each case, ONC will consider the totality of the circumstances in evaluating whether a practice is likely to implicate the statute and to give rise to a violation.

i. Observational Health Information

Although the information blocking provision applies to all EHI, we believe that information blocking concerns are especially pronounced when the conduct at issue has the potential to interfere with the access, exchange, or use of EHI that is created or maintained during the practice of medicine or the delivery of health care services to patients. We refer to such information in this section of the preamble collectively as ''observational health information.'' Such information includes, but is not limited to, health information about a patient that could be captured in a patient record within an EHR and other clinical information management systems; as well as information maintained in administrative and other IT systems when the information is clinically relevant, directly supports patient care, or facilitates the delivery of health care services to consumers. We note that there is a special need for timely, electronic access to this information and that, moreover, the clinical and operational utility of this information is often highly dependent on multiple actors exercising varying forms and degrees of control over the information itself or the technological, contractual, or other means by which it can be accessed, exchanged, and used. Against these indications, practices that adversely impact the access, exchange, or use of observational health information will almost always implicate the information blocking provision.

We note that observational health information may be technically structured or unstructured (such as ''free text''). Therefore, in general, clinicians' notes would constitute observational health information, at least insofar as the notes contain observations or conclusions about a patient or the patient's care. In contrast, we believe certain types of EHI are qualitatively distinct from observational health information, such as EHI that is created through aggregation, algorithms, and other techniques that transform observational health information into fundamentally new data or insights that are not obvious from the observational

information alone. This could include, for example, population-level trends, predictive analytics, risk scores, and EHI used for comparisons and benchmarking activities. Similarly, internally developed quality measures and care protocols are generally distinct from observational health information. In general, we believe that practices that pertain solely to the creation or use of these transformative data and insights would not usually present the very high likelihood of interference described above. However, we emphasize that, depending on the specific facts at issue, practices related to electronic non-observational health information (a type of EHI), such as price information, *could* still be subject to the information blocking provision. We seek comment on this proposed approach and encourage commenters to identify potential practices related to non-observational health information that could raise information blocking concerns.

Finally, we clarify that merely collecting, organizing, formatting, or processing observational health information maintained in EHRs and other source systems does not change the fundamental nature of that EHI or obligations under the information blocking provisions. Likewise, the mere fact that EHI is stored in a proprietary format or has been combined with confidential or proprietary information does not alter the actor's obligations under the information blocking provisions to facilitate access, exchange, and use of the EHI in response to a request. For example, the information blocking provision would be implicated if an actor were to assert proprietary rights in medical vocabularies or code sets in a way that was likely to interfere with the access, exchange, or use of observational health information stored in such formats. However, as noted in section VIII.D.6 of this preamble, under the exception for licensing of interoperability elements on reasonable and non-discriminatory terms, an actor could charge a royalty for access to proprietary data or data coded in a proprietary manner so long as that royalty were offered on reasonable and non-discriminatory terms pursuant to the conditions outlined in the exception.

ii. Purposes for Which Information May be Needed

We believe the information blocking provision will almost always be implicated when a practice interferes with access, exchange, or use of EHI for certain purposes, including but not limited to:

- Providing patients with access to their EHI and the ability to exchange and use it without special effort (*see* section VII.B.4).
- Ensuring that health care professionals, care givers, and other authorized persons have the EHI they need, when and where they need it, to make treatment decisions and effectively coordinate and manage patient care and can use the EHI they may receive from other sources.
- Ensuring that payers and other entities that purchase health care services can obtain the information they need to effectively assess clinical value and promote transparency concerning the quality and costs of health care services.
- Ensuring that health care providers can access, exchange, and use EHI for quality improvement and population health management activities.
- Supporting access, exchange, and use of EHI for patient safety and public health purposes.

The need to ensure that EHI is readily available and usable for these purposes is paramount. Therefore, practices that increase the cost, difficulty, or other burden of accessing, exchanging, or using EHI for these purposes would almost always implicate the information blocking provision. Individuals and entities that develop health IT or have a role in making these technologies and services available should consider the impact of their actions and take steps to support interoperability and avoid impeding the availability or use of EHI.

iii. Control Over Essential Interoperability Elements; Other Circumstances of Reliance or Dependence

An actor may have substantial control over one or more interoperability elements that provide the only reasonable means of accessing, exchanging, or using EHI for a particular purpose. In these circumstances, any practice by the actor that could impede the use of the interoperability elements—or that could unnecessarily increase the cost or other burden of using the elements—would almost always implicate the information blocking provision.

The situation described above is most likely when customers or users are dependent on an actor's technology or services, which can occur for any number of reasons. For example, technological dependence may arise from legal or commercial relations, such as a health care provider's reliance on its EHR developer to ensure that EHI managed on its behalf is accessible and usable when it is needed. Relatedly, most EHI is currently stored in EHRs and other source systems that use proprietary data models or formats. Knowledge of the data models, formats, or other relevant technical information (*e.g.,* proprietary APIs) is necessary to understand the data and make efficient use of it in other applications and technologies. Because this information is routinely treated as confidential or proprietary, the developer's cooperation is required to enable uses of the EHI that go beyond the capabilities provided by the developer's technology. This includes the capability to export complete information sets and to migrate data in the event that a user decides to switch to a different technology.

Separate from these contractual and intellectual property issues, users may become ''locked in'' to a particular technology, HIE, or HIN for financial or business reasons. For example, many health care providers have invested significant resources to adopt EHR technologies—including costs for deployment, customization, data migration, and training—and have tightly integrated these technologies into their information management strategies, clinical workflows, and business operations. As a result, they may be reluctant to switch to other technologies due to the significant cost and disruption this would entail.

Another important driver of technological dependence is the ''network effects'' of health IT adoption, which are amplified by a reliance on technologies and approaches that are not standardized and do not enable seamless interoperability. Consequently, health care providers and other health IT users may gravitate towards and become reliant on the proprietary technologies, HIEs, or HINs that have been adopted by other individuals and entities with whom they have the greatest need to exchange EHI. These effects may be especially pronounced within particular product or geographic areas. For example, a HIN that facilitates certain types of exchange or transactions may be so widely adopted that it is a de facto industry standard. A similar phenomenon may occur within a particular geographic area once a critical mass of hospitals, physicians, or other providers adopt a particular EHR technology, HIE, or HIN.

In these and other analogous circumstances of reliance or dependence, there is a heightened risk that an actor's conduct will interfere with access, exchange, or use of EHI. To assist with compliance, we highlight the following common scenarios, based on our outreach to stakeholders, in which

actors exercise control over key interoperability elements.[109]

• Health IT developers of certified health IT that provide EHR systems or other technologies used to capture EHI at the point of care are in a unique position to control subsequent access to and use of that information.

• HINs and HIEs may be in a unique position to control the flow of information among particular persons or for particular purposes, especially if the HIN or HIE has achieved significant adoption in a particular geographic area or for a particular type of health information use case.

• Similar control over EHI may be exercised by other entities, such as health IT developers of certified health IT, that supply or control proprietary technologies, platforms, or services that are widely adopted by a class of users or that are a ''de facto standard'' for certain types of EHI exchanges or transactions.

• Health care providers within health systems and other entities that provide health IT platforms, infrastructure, or information sharing policies may have a degree of control over interoperability or the movement of data within a geographic area that is functionally equivalent to the control exercised by a dominant health IT developer, HIN, or HIE.

To avoid violating the information blocking provision, actors with control over interoperability elements should be careful not to engage in practices that exclude persons from the use of those elements or create artificial costs or other impediments to their use.

We encourage comment on these and other circumstances that may present an especially high likelihood that a practice will interfere with access, exchange, or use of EHI within the meaning of the information blocking provision.

c. Examples of Practices Likely To Interfere With Access, Exchange, or Use of EHI

To further clarify the scope of the information blocking provision, below we describe several types of practices that would be likely to interfere with access, exchange, or use of EHI. These examples clarify and expand on those set forth in section 3022(a)(2) of the PHSA.

Because information blocking can take many forms, we emphasize that the categories of practices described below are illustrative only and do not provide an exhaustive list or comprehensive description of practices that may implicate the information blocking provision and its penalties. We also reiterate that to implicate the provision is not necessarily to violate it, and that each case will turn on its own unique facts. For instance, a practice that seemingly meets the statutory definition of information blocking would not be information blocking if it was required by law, if one or more elements of the definition were not met, or if it was covered by one of the proposed exceptions for certain reasonable and necessary activities detailed in section VIII.D of this preamble. For the purposes of the following discussion, we do not consider the applicability of any exceptions proposed in section VIII.D of this preamble; we therefore strongly encourage readers to review that section in conjunction with the discussion of practices in this section below.

i. Restrictions on Access, Exchange, or Use

The information blocking provision establishes penalties, including civil monetary penalties, or requires appropriate disincentives, for practices that restrict access, exchange, or use of EHI for permissible purposes. For example, section 3022(a)(2)(A) of the PHSA states that information blocking may include practices that restrict authorized access, exchange, or use for treatment and other permitted purposes under applicable law. Section 3022(a)(2)(C)(i) of the PHSA states that information blocking may include implementing health IT in ways that are likely to restrict the access, exchange, or use of EHI with respect to exporting complete information sets or in transitioning between health IT systems.

One means by which actors may restrict access, exchange, or use of EHI is through formal restrictions. These may be expressed in contract or license terms, EHI sharing policies, organizational policies or procedures, or other instruments or documents that set forth requirements related to EHI or health IT. Additionally, in the absence of an express contractual restriction, an actor may achieve the same result by exercising intellectual property or other rights in ways that restrict access, exchange, or use. As an illustration, the following non-exhaustive examples illustrate types of formal restrictions that would likely implicate the information blocking provision. As stated above, the examples throughout this section VIII.C.5.c. are presented without consideration to whether a proposed exception applies, and readers are encouraged to familiarize themselves with section VIII.D of this preamble.

• A health system's internal policies or procedures require staff to obtain an individual's written consent before sharing any of a patient's EHI with unaffiliated providers for treatment purposes even though obtaining an individual's consent is not required by state or federal law.

• An EHR developer's software license agreement prohibits a customer from disclosing to its IT contractors certain technical interoperability information without which the customer and its IT contractors cannot efficiently export and convert EHI for use in other applications.

• A HIN's participation agreement prohibits entities that receive EHI through the HIN from transmitting that EHI to entities who are not participants of the HIN.

• An EHR developer sues to prevent a clinical data registry from providing interfaces to physicians who use the developer's EHR technology and wish to submit EHI to the registry. The EHR developer claims that the registry is infringing the developer's copyright in its database because the interface incorporates data mapping that references the table headings and rows of the EHR database in which the EHI is stored.

Access, exchange, or use of EHI can also be restricted in less formal ways. The information blocking provision would be implicated, for example, where an actor simply refuses to exchange or to facilitate the access or use of EHI, either as a general practice or in isolated instances. The refusal may be expressly stated, or it may be implied from the actor's conduct, as where the actor ignores requests to share EHI or provide interoperability elements; gives implausible reasons for not doing so; or insists on terms or conditions that are so objectively unreasonable that they amount to a refusal to provide access, exchange, or use of the EHI. Some examples of informal restrictions include, but are not limited to:

• A health IT developer of certified health IT refuses to license interoperability elements that are reasonably necessary for the developer's customers, their IT contractors, and other health IT developers to develop and deploy software that will work with the certified health IT.

• A health system incorrectly claims that the HIPAA Rules or other legal requirements preclude it from exchanging EHI with unaffiliated providers.

[109] As an important clarification, we note that control over interoperability elements may exist with or without the actor's ability to manipulate the price of the interoperability elements in the market.

• An EHR developer ostensibly allows third-party developers to deploy apps that are interoperable with its EHR system. However, as a condition of doing so, the third-party developers must provide their source code and grant the EHR developer the right to use it for its own purposes—terms that almost no developer would willingly accept.

• A provider notifies its EHR developer of its intent to switch to another EHR system and requests a complete export of its EHI. The developer will provide only the EHI in a PDF format, even though it already can and does produce the data in a commercially reasonable structured format.

We emphasize that restrictions on access, exchange, or use that are required by law would not implicate the information blocking provision. Moreover, we recognize that some restrictions, while not required by law, may be reasonable and necessary for the privacy and security of individuals' EHI; such practices may qualify for protection under the exceptions proposed in section VIII.D.2 and 3 of this preamble.

ii. Limiting or Restricting the Interoperability of Health IT

The information blocking provision includes practices that restrict the access, exchange, or use of EHI in various ways (*see* section 3022(a)(2) of the PHSA). These practices could include, for example, disabling or restricting the use of a capability that enables users to share EHI with users of other systems or to provide access to EHI to certain types of persons or for certain purposes that are legally permissible. In addition, the information blocking provision would be implicated where an actor configures or otherwise implements technology in ways that limit the types of data elements that can be exported or used from the technology. Other practices that would be suspect include configuring capabilities in a way that removes important context, structure, or meaning from the EHI, or that makes the data less accurate, complete, or usable for important purposes for which it may be needed. Likewise, implementing capabilities in ways that create unnecessary delays or response times, or that otherwise limit the timeliness of EHI accessed or exchanged, would interfere with the access, exchange, and use of that information and would therefore implicate the information blocking provision. We note that any conclusions regarding such interference would be based on fact-finding specific to each case and would need to consider the applicability of an exception.

We propose that the information blocking provision would be implicated if an actor were to deploy technological measures that limit or restrict the ability to reverse engineer the functional aspects of technology in order to develop means for extracting and using EHI maintained in the technology. This may include, for example, employing technological protection measures that, if circumvented, would trigger liability under the Digital Millennium Copyright Act (*see* 17 U.S.C. 1201) or other laws.

The following hypothetical situations illustrate some (though not all) of the types of practices described above and which would implicate the information blocking provision.

• A health system implements locally-hosted EHR technology certified to proposed § 170.315(g)(10) (the health system acts as an API Data Provider as defined by § 170.102). As required by proposed § 170.404(b)(2), the technology developer provides the health system with the capability to automatically publish its production endpoints (*i.e.,* the internet servers that an app must ''call'' and interact with in order to request and exchange patient data). The health system chooses not to enable this capability, however, and provides the production endpoint information only to apps it specifically approves. This prevents other applications—and patients that use them—from accessing data that should be made readily accessible via standardized APIs.

• A hospital directs its EHR developer to configure its technology so that users cannot easily send electronic patient referrals and associated EHI to unaffiliated providers, even when the user knows the Direct address and/or identity (*i.e.,* National Provider Identifier) of the unaffiliated provider.

• An EHR developer that prevents (such as by way of imposing exorbitant fees unrelated to the developer's costs, or by some technological means) a third-party clinical decision support (CDS) app from writing EHI to the records maintained by the EHR developer on behalf of a health care provider (despite the provider authorizing the third-party app developer's use of EHI) because the EHR developer: (1) Offers a competing CDS software to the third-party app; and (2) includes functionality (*e.g.,* APIs) in its health IT that would provide the third party with the technical capability to modify those records as desired by the health care provider.

• Although an EHR developer's patient portal offers the capability for patients to directly transmit or request for direct transmission of their EHI to a third party, the developer's customers (*e.g.,* health care providers) choose not to enable this capability.

• A health care provider has the capability to provide same-day access to EHI in a form and format requested by a patient or a patient's health care provider, but takes several days to respond.

iii. Impeding Innovations and Advancements in Access, Exchange, or Use or Health IT-Enabled Care Delivery

The information blocking provision encompasses practices that create impediments to innovations and advancements to the access, exchange, and use of EHI, including care delivery enabled by health IT (section 3022(a)(2)(C)(ii) of the PHSA). Importantly, the information blocking provision would be implicated and penalties may apply if an actor were to engage in exclusionary, discriminatory, or other practices that impede the development, dissemination, or use of interoperable technologies and services that enhance access, exchange, or use of EHI.

Most acutely, the information blocking provision would be implicated if an actor were to refuse to license or allow the disclosure of interoperability elements to persons who require those elements to develop and provide interoperable technologies or services—including those that might complement or compete with the actor's own technology or services. The same would be true if the actor were to allow access to interoperability elements but were to restrict their use for these purposes. The following examples, which are not exhaustive, illustrate practices that would likely implicate the information blocking provision by interfering with access, exchange, or use of EHI:

• A health IT developer of certified health IT refuses to license an API's interoperability elements, to grant the rights necessary to commercially distribute applications that use the API's interoperability elements, or to provide the related services necessary to enable the use of such applications in production environments.

• An EHR developer of certified health IT requires third-party applications to be ''vetted'' for security before use but does not promptly conduct the vetting or conducts the vetting in a discriminatory or exclusionary manner.

• A health IT developer of certified health IT refuses to license interoperability elements that other software applications require to efficiently access, exchange, and use

EHI maintained in the developer's technology.

Rather than restricting interoperability elements, an actor may insist on terms or conditions that are burdensome and discourage their use. These practices would implicate the information blocking provision for the reasons described above. Consider the following non-exhaustive examples:

• An EHR developer of certified health IT maintains an ''app store'' through which other developers can have ''apps'' listed that run natively on the EHR developer's platform. However, if an app ''competes'' with the EHR developer's apps or apps it plans to develop, the developer *requires* that the app developer grant the developer the right to use the app's source code.

• A health care provider engages a systems integrator to develop an interface engine. However, the provider's license agreement with its EHR developer prohibits it from disclosing technical documentation that the systems integrator needs to perform the work. The EHR developer states that it will only permit the systems integrator to access the documentation if all of its employees sign a broad non-compete agreement that would effectively bar them from working for any other health IT companies.

The information blocking provision would be implicated also if an actor were to discourage efforts to develop or use interoperable technologies or services by exercising its influence over customers, users, or other persons, as in the following non-exhaustive examples:

• An EHR developer of certified health IT maintains an ''app store'' through which other developers can have ''apps'' listed that run natively on the EHR developer's platform. The EHR developer charges app developers a substantial fee for this service unless an app developer agrees not to deploy the app in any other EHR developers' app stores.

• A hospital is working with several health IT developers to develop an application that will enable ambulatory providers who use different EHR systems to access and update patient data in the hospital's EHR system from within their ambulatory EHR workflows. The inpatient EHR developer, being a health IT developer of certified health IT, pressures the hospital to abandon this project, stating that if it does not it will no longer receive the latest updates and features for its inpatient EHR system.

• A health IT developer of certified health IT discourages customers from procuring data integration capabilities from a third-party developer, claiming that it will be providing such capabilities free of charge in the next release of its product. In reality, the capabilities it is developing are more limited in scope and are still 12–18 months from being production-ready.

• A health system insists that local physicians adopt its EHR platform, which provides limited connectivity with competing hospitals and facilities. The health system threatens to revoke admitting privileges for physicians that do not comply.

Similar concerns would arise were an actor to engage in discriminatory practices—such as imposing unnecessary and burdensome administrative, technical, contractual, or other requirements on certain persons or classes of persons—that interfere with access and exchange or EHI by frustrating or discouraging efforts to enable interoperability. The following non-exhaustive examples illustrate some ways this could occur:

• An HIN charges additional fees, requires more stringent testing or certification requirements, or imposes additional terms for participants that are competitors, are potential competitors, or may use EHI obtained via the HIN in a way that facilitates competition with the HIN.

• A health care provider imposes one set of fees and terms to establish interfaces or data sharing arrangements with several registries and exchanges, but offers another more costly or significantly onerous set of terms to establish substantially similar interfaces and arrangements with an HIE or HIN that is used primarily by health plans that purchase health care services from the provider at negotiated reduced rates.

• A health IT developer of certified health IT charges customers fees, throttles speeds, or limits the number of records they can export when exchanging EHI with a regional HIE that supports exchange among users of competing health IT products, but does not impose like fees or limitations when its customers exchange EHI with enterprise HIEs that primarily serve users of the developer's own technology.

• As a condition of disclosing interoperability elements to third-party developers, an EHR developer requires third-party developers to enter into business associate agreements with all of the EHR developer's covered entity customers, even if the work being done is not for the benefit of the covered entities.

• A health IT developer of certified health IT takes significantly longer to provide or update interfaces that facilitate the exchange of EHI with users of competing technologies or services.

We clarify that not all instances of differential treatment would necessarily constitute a discriminatory practice that implicates the information blocking provision. For example, different fee structures or other terms may reflect genuine differences in the cost, quality, or value of the EHI and the effort required to provide access, exchange, or use. We also note that, in certain circumstances, it may be reasonable and necessary for an actor to restrict or impose reasonable and non-discriminatory terms or conditions on the use of interoperability elements, even though such practices could implicate the information blocking provision. For this reason, we propose in section VIII.D.6 of this preamble to establish a narrow exception that would apply to these types of practices.

iv. Rent-Seeking and Other Opportunistic Pricing Practices

Certain practices that artificially increase the cost and expense associated with accessing, exchanging, and using EHI will implicate the information blocking provision. Such practices are plainly contrary to the information blocking provision and the concerns that motivated its enactment.

An actor may seek to extract profits or capture revenue streams that would be unobtainable without control of a technology or other interoperability elements that are necessary to enable or facilitate access, exchange, or use of EHI. As discussed in section VIII.C.5.b.iii of this proposed rule, most EHI is currently stored in EHRs and other source systems that use proprietary data models or formats; this puts EHR developers (and other actors that control data models or standards) in a unique position to block access to (including the export and portability of) EHI for use in competing systems or applications, or to charge rents for access to the basic technical information needed to accomplish the access, exchange, or use of EHI for these purposes. These information blocking concerns may be compounded to the extent that EHR developers do not disclose, in advance, the fees they will charge for interfaces, data export, data portability, and other interoperability-related services (*see* 80 FR 62719; 80 FR 16880–81). We note that these concerns are not limited to EHR developers. Other actors who exercise substantial control over EHI or essential interoperability elements may engage in analogous behaviors that would implicate the information blocking provision.

To illustrate, we provide the following non-exhaustive examples, which reflect some of the more common types of rent-seeking and opportunistic behaviors of which we are aware and that are likely to interfere with access, exchange, or use of EHI:

- An EHR developer of certified health IT charges customers a fee to provide interfaces, connections, data export, data conversion or migration, or other interoperability services, where the amount of the fee exceeds the actual costs that the developer reasonably incurred to provide the services to the particular customer(s).
- An EHR developer of certified health IT charges a fee to perform an export using the EHI export capability proposed in § 170.315(b)(10) for the purposes of switching health IT systems or to provide patients access to EHI.
- An EHR developer of certified health IT charges more to export or use EHI in certain situations or for certain purposes, such as when a customer is transitioning to a competing technology or attempting to export data for use with a HIE, third-party application, or other technology or service that competes with the revenue opportunities associated with the EHR developer's own suite of products and services.
- An EHR developer of certified health IT interposes itself between a customer and a third-party developer, insisting that the developer pay a licensing fee, royalty, or other payment in exchange for permission to access the EHR system or related documentation, where the fee is not reasonably necessary to cover any additional costs the EHR developer incurs from the third-party developer's activities.
- An analytics company provides services to the customers of an EHR developer of certified health IT, including de-identifying customer EHI and combining it with other data to identify areas for quality improvement. The EHR developer insists on a revenue sharing arrangement whereby it would receive a percentage of the revenue generated from these activities in return for facilitating access to its customers' EHI, which turns out to be disadvantageous to customers. The revenue the EHR developer would receive exceeds its reasonable costs of facilitating the access to EHI.

The information blocking provision would clearly be implicated by these and other practices by which an actor profits from its unreasonable control over EHI or interoperability elements without adding any efficiency to the health care system or serving any other procompetitive purpose. But the reach of the information blocking provision is not limited to these types of practices. We interpret the definition of information blocking to encompass *any* fee that materially discourages or otherwise imposes a material impediment to access, exchange, or use of EHI. We use the term ''fee'' in the broadest possible sense to refer to any present or future obligation to pay money or provide any other thing of value and propose to include this definition in § 171.102. We believe this scope may be broader than necessary to address genuine information blocking concerns and could unnecessarily diminish investment and innovation in interoperable technologies and services. Therefore, as discussed in section VIII.D.4 of this preamble, we propose to create an exception that, subject to certain conditions, would permit the recovery of costs that are reasonably incurred to provide access, exchange, and use of EHI. We refer readers to that section for additional details regarding this proposal.

v. Non-Standard Implementation Practices

Section 3022(a)(2)(B) of the PHSA states that information blocking may include implementing health IT in non-standard ways that substantially increase the complexity or burden of accessing, exchanging, or using EHI. In general, this type of interference is likely to occur when, despite the availability of generally accepted technical, policy, or other approaches that are suitable for achieving a particular implementation objective, an actor does not implement the standard, does not implement updates to the standard, or implements the standard in a way that materially deviates from its formal specifications. These practices lead to unnecessary complexity and burden, such as the additional cost and effort required to implement and maintain ''point-to-point'' connections, custom-built interfaces, and one-off trust agreements.

While each case will necessarily depend on its individual facts, and while we recognize that the development and adoption of standards across the health IT industry is an ongoing process, we propose that the information blocking provision would be implicated in at least two distinct sets of circumstances. First, information blocking may arise where an actor chooses not to adopt, or to materially deviate from, relevant standards, implementation specifications, and certification criteria adopted by the Secretary under section 3004 of the PHSA. Second, even where no federally adopted or identified standard exists, if a particular implementation approach has been broadly adopted in a relevant industry segment, deviations from that approach would be suspect unless strictly necessary to achieve substantial efficiencies.

To further illustrate these types of practices that would implicate the information blocking provision, we provide the following non-exhaustive examples of conduct that would be likely to interfere with access, exchange, or use of EHI:

- An EHR developer of certified health IT implements the C–CDA for receiving transitions of care summaries but only sends transitions of care summaries in a proprietary or outmoded format.
- A health IT developer of certified health IT adheres to the ''required'' portions of a widely adopted industry standard but chooses to implement proprietary approaches for ''optional'' parts of the standard when other interoperable means are readily available.

Even where no standards exist for a particular purpose, actors should not design or implement health IT in non-standard ways that unnecessarily increase the costs, complexity, and other burden of accessing, exchanging, or using EHI. For example, an EHR developer of certified health IT designs its database tables in a way that is unreasonably difficult to ''map'' to a non-proprietary format, which is a necessary prerequisite to converting the EHI to a format that can be used in other software applications. When a customer requests the capability to export EHI to a clinical data registry, the EHR developer quotes substantial costs resulting from the need to write custom code to enable this functionality. Based on these facts, the fees do not reflect costs that are reasonably incurred to provide the service and are instead the result of the developer's impractical design choices. We are aware that some actors attribute certain non-standard implementations on legacy systems that the actor did not themselves design but which have to be integrated into the actor's health IT. Such instances will be considered on a case by case basis.

Again, we reiterate that information blocking can take many forms and that the practices (and categories of practices) described above do not provide an exhaustive list or comprehensive description of practices that may implicate the information blocking provision.

6. Applicability of Exceptions

a. Reasonable and Necessary Activities

As discussed above, section 3022(a)(3) authorizes the Secretary to identify, through notice and comment rulemaking, reasonable and necessary *activities* that do not constitute information blocking for purposes of the definition set forth in section 3022(a)(1). Separately, the Cures Act identifies at section 3022(a)(1) *practices* that contravene the definition of information blocking. Following this Cures Act terminology, conduct that implicates the information blocking provision and that does not fall within one of the exceptions described in section VIII.D of this preamble, or does not meet all conditions for an exception, would be considered a ''practice.'' Conduct that falls within an exception and meets all the applicable conditions for that exception would be considered an ''activity.'' The challenge with this distinction is that when examining conduct that is the subject of an information blocking claim— an actor's actions that likely interfered with access, exchange, or use of EHI—it can be illusory to distinguish, on its face, conduct that is a *practice* and conduct that is an *activity.* Indeed, conduct that implicates the information blocking provision but falls within an exception could nonetheless be considered information blocking in the event that the actor has not satisfied the conditions applicable to that exception.

While we acknowledge the terminology used in the Cures Act, we propose to use the term ''practice'' throughout this proposed rule when we describe conduct that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, regardless of whether that conduct meets the conditions for an exception to the information blocking provision. Consistent with this approach, when identifying reasonable and necessary activities in §§ 171.200 through 171.206, we describe *practices* that, if all the applicable conditions are met, are reasonable and necessary and not information blocking. We have taken this approach, in part, because we believe that to adopt the terminology of activity to describe conduct that may or may not be information blocking would confuse the reader and obfuscate our intent in certain circumstances. As an illustration, a health care provider may implement an organizational security policy that limits access, exchange, or use of certain information to certain users (*e.g.,* role-based access). Prior to determining whether the implementation of the security policy is reasonable and necessary under the circumstances, such conduct would be considered a ''practice'' that implicates the information blocking provision. However, it may later be determined that such conduct is reasonable and necessary and would then be considered an ''activity.'' Due to these types of scenarios, we contend that the better approach is to use one term—practice—throughout the proposed rule and clarify when describing the conduct at issue whether it is a practice that is information blocking, a practice that implicates the information blocking provision, or a practice that is reasonable and necessary and not information blocking.

b. Treatment of Different Types of Actors

The proposed exceptions would apply to health care providers, health IT developers of certified health IT, HIEs, and HINs who engage in certain practices covered by an exception, provided that all applicable conditions of the exception are satisfied at all relevant times and for each practice for which the exception is sought. The exceptions are generally applicable to all actors. However, in some instances we propose conditions within an exception that apply to a particular type of actor.

c. Establishing That Activities and Practices Meet the Conditions of an Exception

We propose that, in the event of an investigation of an information blocking complaint, an actor must demonstrate that an exception is applicable and that the actor met all relevant conditions of the exception at all relevant times and for each practice for which the exception is sought. We consider this allocation of proof to be a substantive condition of the proposed exceptions. As a practical matter, we propose that actors are in the best position to demonstrate compliance with the conditions of the proposed exceptions and to produce the detailed evidence necessary to demonstrate that compliance. We request comment about the types of documentation and/or standardized methods that an actor may use to demonstrate compliance with the exception conditions.

D. Proposed Exceptions to the Information Blocking Provision

We propose to establish seven exceptions to the information blocking provision. The exceptions would apply to certain activities that may technically meet the definition of information blocking but that are reasonable and necessary to further the underlying public policies of the information blocking provision.

The seven proposed exceptions are based on three related policy considerations. First, each exception is limited to certain activities that clearly advance the aims of the information blocking provision. These reasonable and necessary activities include providing appropriate protections to prevent harm to patients and others; promoting the privacy and security of EHI; promoting competition and innovation in health IT and its use to provide health care services to consumers, and to develop more efficient means of health care delivery; and allowing system downtime in order to implement upgrades, repairs, and other changes to health IT. Second, each exception addresses a significant risk that regulated actors will not engage in these beneficial activities because of uncertainty concerning the breadth or applicability of the information blocking provision. Finally, each exception is subject to strict conditions to ensure that it is limited to activities that are reasonable and necessary.

The first three exceptions, set forth in VIII.D.1–D.3, extend to certain activities that are reasonable and necessary to prevent harm to patients and others; promote the privacy of EHI; and promote the security of EHI, subject to strict conditions to prevent the exceptions from being misused. We believe that without these exceptions, actors may be reluctant to engage in the types of reasonable and necessary activities described below, and that this could erode trust in the health IT ecosystem and undermine efforts to provide access and facilitate the exchange and use of EHI for important purposes. Such a result would be contrary to the purpose of the information blocking provision and the broader policies of the Cures Act.

The next three exceptions, set forth in VIII.D.4–D.6, address activities that are reasonable and necessary to promote competition and consumer welfare. First, we propose to permit the recovery of certain types of reasonable costs incurred to provide technology and services that enable access to EHI and facilitate the exchange and use of that information, provided certain conditions are met. Second, we propose to permit an actor to decline to provide access, exchange, or use of EHI in a manner that is infeasible, subject to a duty to provide a reasonable alternative. And, third, we propose an exception that would permit an actor to license interoperability elements on reasonable

and non-discriminatory terms. These exceptions would be subject to strict conditions to ensure that they do not extend protection to practices that raise information blocking concerns.

The last exception, set forth in VIII.D.7, recognizes that it may be reasonable and necessary for actors to make health IT temporarily unavailable for the benefit of the overall performance of health IT. This exception would permit an actor to make the operation of health IT unavailable in order to implement upgrades, repairs, and other changes.

As context for the exceptions proposed below in VIII.D.4–D.6, we note that addressing information blocking is critical for promoting competition and innovation in health IT and for the delivery of health care services to consumers. Indeed, the information blocking provision itself expressly addresses practices that impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health IT (section 3022(a)(2)(C)(ii) of the PHSA). As discussed in section VIII.C.5.b.iii of this preamble, health IT developers of certified health IT, HIEs, HINs, and, in some instances, health care providers may exploit their control over interoperability elements to create barriers to entry for competing technologies and services that offer greater value for health IT customers and users, provide new or improved capabilities, and enable more robust access, exchange, and use of EHI.[110] More than this, information blocking may harm competition not just in health IT markets, but also in markets for health care services.[111] Dominant providers in these markets may leverage their control over technology to limit patient mobility and choice.[112] They may also pressure independent providers to adopt expensive, hospital-centric technologies that do not suit their workflows, limit their ability to share information with unaffiliated providers, and make it difficult to adopt or use alternative technologies that could offer greater efficiency and other benefits.[113] The technological dependence resulting from these practices can be a barrier to entry by would-be competitors. It can also make independent providers vulnerable to acquisition or induce them into exclusive arrangements that enhance the market power of incumbent providers, while preventing the formation of clinically-integrated products and networks that offer more choice and better value to consumers and purchasers of health care services.

Section 3022(a)(5) of the PHSA provides that the Secretary may consult with the Federal Trade Commission (FTC) in defining practices that do not constitute information blocking because they are necessary to promote competition and consumer welfare. We appreciate the expertise and informal technical assistance of FTC staff, which we have taken into consideration in developing the exceptions described in VIII.D.4–D.6 of this preamble. We note that the language in the Cures Act regarding information blocking is substantively and substantially different from the language and goals in the antitrust laws enforced by the FTC. We view the Cures Act as authorizing ONC and OIG to regulate conduct that may be considered permissible under the antitrust laws. On this basis, this proposed rule requires that actors who control interoperability elements cooperate with individuals and entities that require those elements for the purpose of developing, disseminating, and enabling technologies and services that can interoperate with the actor's technology.

We emphasize that ONC is taking this approach because we view patients as having an overwhelming interest in EHI about themselves, and particularly observational health information (see the discussion in section VIII.C.4.b of this preamble). As such, access to EHI, and the EHI itself, should not be traded or sold by those actors who are custodians of EHI or who control its access, exchange, or use. We emphasize that such actors should not be able to charge fees for providing electronic access, exchange, or use of patients' EHI. We propose that actors should be required to share EHI unless they are prohibited from doing so under an existing law or are covered by one of the exceptions detailed in this preamble. In addition, any remedy sought or action taken by HHS under the information blocking provision would be independent from the antitrust laws and would not prevent FTC or DOJ from taking action with regard to the same actor or conduct.

We request comment on the following seven proposed exceptions, including whether they will achieve our stated policy goals.

1. Preventing Harm

We propose to establish an exception to the information blocking provision for practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met. The exception and corresponding conditions are set forth in the proposed regulation text in § 171.201.

This proposed exception would acknowledge the public interest in protecting patients and other persons against unreasonable risks of harm that, in certain narrowly defined circumstances described below, justify practices that are likely to interfere with access, exchange, or use of EHI and that would implicate the information blocking provision in the absence of an exception.

The exception would be subject to strict conditions, which we believe are necessary to prevent patient safety from being used as a pretext for information blocking or as a post hoc rationalization for practices that are not reasonable and necessary to address material risks of harm to a patient or another person.

We have adopted the terminology of ''patient'' to denote the context in which the threat of harm arises. That is, this proposed exception has been designed to recognize certain practices taken for the benefit of recipients of health care—those individuals whose EHI is at issue—and other persons whose information may be recorded in that EHI or who may be at risk of harm because of the access, use, or exchange of EHI. The use of the term ''patient'' does not require, other than in the context of the risk of harm determined by a licensed health care professional (*see* § 171.201(a)(3)), that an actor seeking to benefit from this exception needs to have a clinician-patient relationship with the individual (or individuals) at risk of harm. Indeed, a health IT developer of certified health IT would be able to benefit from this exception in connection with practices undertaken for the benefit of individuals receiving (or having received, or expected to receive) care from a health care provider that uses the developer's health IT. Similarly, an HIE or HIN that exchanges or facilitates the exchange of EHI would

[110] *See also* Martin Gaynor, Farzad Mostashari, and Paul B. Ginsberg, *Making Health Care Markets Work: Competition Policy for Health Care,* 16–17 (Apr. 2017), available at *http://heinz.cmu.edu/news/news-detail/index.aspx?nid=3930.*

[111] *See, e.g.,* Keynote Address of FTC Chairwoman Edith Ramirez, Antitrust in Healthcare Conference Arlington, VA (May 12, 2016), *available at https://www.ftc.gov/system/files/documents/public_statements/950143/160519antitrust healthcarekeynote.pdf.*

[112] *See, e.g.,* Martin Gaynor, Farzad Mostashari, and Paul B. Ginsberg, *Making Health Care Markets Work: Competition Policy for Health Care,* 16–17 (Apr. 2017), *available at http://heinz.cmu.edu/news/news-detail/index.aspx?nid=3930.*

[113] *See, e.g., Healthcare Research Firm Toughens Survey Standards as More CIOs Reap the Profits of Reselling Vendor Software,* Black Book, *available at http://www.prweb.com/releases/2015/02/prweb12530856.htm;* Arthur Allen, *Connecticut Law Bans EHR-linked Information Blocking, Politico.com* (Oct. 29, 2015).

be able to benefit from this exception in connection with the activities carried out by the HIE or HIN for or at the direction of a health care provider.

Patient Harm Risks That Would Be Cognizable Under This Exception

Consistent with the definition of information blocking, we have identified certain risks to patient harm that arise in the context of access, exchange, or use of EHI. To qualify for this proposed exception, an actor's practice must respond to a risk that is cognizable under this exception.

Risk of Corrupt or Inaccurate Data Being Recorded or Incorporated in a Patient's Electronic Health Record

The exception may apply to practices that prevent harm arising from corrupted or inaccurate EHI being recorded or incorporated in a patient's electronic health record. Users of health IT systems strive to maintain accurate electronic health records by carefully inputting EHI and verifying existing EHI. Occasionally a clinician or other user of health IT is presented with EHI that, due to a failure of the technology, is either entirely incorrect or contains inaccurate information. At other times, EHI could become corrupted. In these cases, the sharing or integration of such EHI could lead to inaccuracies in the patient's electronic health record that then run the risk of being propagated further. We note, however, that known inaccuracies in some data within a record may not be sufficient justification to withhold the entire record if the remainder of the patient's EHI could be effectively shared without also presenting the known incorrect or corrupted information as if it were trustworthy. Also, we would expect that once information is known to be inaccurate or corrupted, a health care provider holding that record would, for example, take action to cure the inaccuracy or corruption. We understand that in the ordinary course of practice, and consistent with professional and legal standards for clinical record keeping, health care providers take appropriate action to remediate known problems with EHI and restore a record as a whole to be safely usable, and therefore safely sharable.

This recognized risk is limited to corruption and inaccuracies caused by performance and technical issues affecting health IT. For example, this exception may be relevant if certified health IT were to incorrectly present an old and superseded version of a medication list, or when only partial copies of laboratory tests are being linked to a patient when the patient's record is exchanged. However, this recognized risk does not extend to purported accuracy issues arising from the incompleteness of a patient's electronic health record generally. Electronic health records, like the paper charts they replaced, are inevitably imperfect records. Many patients see multiple health care providers and so it is unlikely that any single health care provider's record will provide a complete picture of a patient's health. Some patients intentionally keep certain information secret even from their health care providers, and others fail to share potentially critical information with their health care providers because they forget to, or simply do not understand its clinical significance.

While the access, exchange, or use of EHI in these situations could give rise to the risk of harm if the EHI was relied on without qualification, such reliance does not accord with our understanding of clinical practice, as the risk of incompleteness resulting from patients having multiple providers, or from errors of omission by patients and their care providers, is not unique to electronic health records or their interoperable exchange. Therefore, the risk that the EHI a given health care provider holds for a given patient may not be a perfectly complete record of that patient's health or care will not be recognized as being sufficient to support an actor qualifying for this exception in the face of a claim of information blocking.

We also acknowledge that certain federal and state laws, such as 42 CFR part 2 and state medical record laws, require an actor to obtain an individual's written consent before sharing health information. However, we propose that an actor would not be able to benefit from this exception on the basis of a perceived risk arising from exchanging or providing access to EHI when the EHI exchanged or made accessible does not include certain information due to a patient's decision not to consent to its disclosure. For example, this exception would not recognize an actor's conduct in not providing access, exchange, or use of a patient's electronic health record on the basis that the patient's failure to consent to the disclosure of substance abuse treatment information made the patient's record incomplete and thus inaccurate.

Risk of Misidentifying a Patient or Patient's Electronic Health Information

The exception may apply to practices that are designed to promote data quality and integrity and support health IT applications properly identifying and matching patient records or EHI. Accurately identifying patients and correctly attributing their EHI to them is a complex task and involves layers of safeguards, including verification of a patient's identity, proper registration in health IT systems, physical identification such as wristbands, and usability and implementation decisions such as ensuring the display of a patient's name and date of birth on every screen of the patient's electronic chart. When a clinician or other health IT user may know or reasonably suspect that specific EHI in a patient's record is or may be misattributed, either within a local record or as received through EHI exchange, it would be reasonable for them to avoid sharing or incorporating the EHI that they know would, or reasonably suspect could, propagate errors in the patient's records and thus pose the attendant risks to the patient. As discussed below, an actor's response to this risk would need to be no broader than necessary to mitigate the risk of harm arising from the potentially misidentified record or misattributed data. A health IT developer of certified health IT could not, for example, refuse to provide a batch export on the basis that the exported records may contain a misidentified record. Similarly, a health care provider that identified that a particular piece of information had been misattributed to a patient would not be excused from exchanging or providing access to all other EHI about the patient that had not been misattributed.

Determination by a Licensed Health Care Professional That the Disclosure of EHI Is Reasonably Likely To Endanger Life or Physical Safety

The exception may permit certain restrictions on the disclosure of an individual's EHI in circumstances where a licensed health care professional has determined, in the exercise of professional judgment, that the disclosure is reasonably likely to endanger the life or physical safety of the patient or another person. This would include the situation where a covered entity elected not to treat a person as the personal representative of an individual in situations of potential abuse or endangerment, including in accordance with 45 CFR 164.502(g)(5). In certain cases, the clinician may have individualized knowledge stemming from the clinician-patient relationship that, for a particular patient and for that patient's circumstances, harm could result if certain EHI were shared or transmitted electronically. Consistent with the HIPAA Privacy Rule, a

decision not to provide access, exchange, or use of EHI on this basis would be subject to any right that an affected individual is afforded under applicable federal or state laws to have the determination reviewed and potentially reversed.

We request comment on whether the categories of harm described above capture the full range of safety risks that might arise directly from accessing, exchanging, or using EHI. We also request comment on whether we should consider other types of patient safety risks related to data quality and integrity concerns, or that may have a less proximate connection to EHI but that could provide a reasonable and necessary basis for an actor to restrict or otherwise impede access, exchange, or use of EHI in appropriate circumstances. We ask that commenters provide detailed rationale for any suggested revisions to these categories, including additional conditions that may be necessary to ensure that the exception is tailored and does not extend protection to practices that are not reasonable and necessary to promote patient safety and that could present information blocking concerns.

Reasonable Belief That Practice Was Necessary to Directly and Substantially Reduce the Likelihood of Harm

To qualify for this exception, an actor must have had a reasonable belief that the practice or practices will directly and substantially reduce the likelihood of harm to a patient or another person. As discussed above, the type of risk must also be cognizable under this exception.

An actor could meet this condition in two ways.

Qualifying Organizational Policy

In most cases, we anticipate that the actor would demonstrate that the practices it engaged in were consistent with an organizational policy that was objectively reasonable and no broader than necessary for the type of patient safety risks at issue. In these circumstances, we propose that an actor's policy would need to satisfy the following requirements.

First, we propose that the policy must be in writing.

Second, it must have been developed with meaningful input from clinical, technical, and other appropriate staff or others who have expertise or insight relevant to the risk of harm that the policy addresses. This condition would not be met if, for example, a hospital imposed top-down information sharing policies or workflows established by the hospital's EHR developer and approved by hospital administrators without meaningful input from the medical staff, IT department, and front-line clinicians who would implement, and thus be affected by, the policy and are in the best position to gauge how effective it will be at mitigating patient safety risks.

Third, we propose that the policy must have been implemented in a consistent and non-discriminatory manner. As part of this condition, the actor must have taken reasonable steps to educate its directors, officers, employees, contractors, and authorized personnel on how to apply the policy and to provide appropriate oversight to ensure that the policy is not applied in an arbitrary, discriminatory, or otherwise inappropriate manner. This condition would not be met if, for example, a policy or practice were based on factors that lacked a direct and substantial correlation with the particular risk of harm at issue.

Last, we propose that the policy must have been be no broader than necessary for the specific risk or type of risk at issue. For example, as evidence that the policy is no broader than necessary, the policy would need to identify the relevant risks and follow an approach to mitigating those risks that is based on current patient safety evidence and best practices, supplemented by input from clinical, technical, and other staff or others who are in the best position to make judgments about the policy's effectiveness, as discussed above. Further evidence that the policy was no broader than necessary would be whether the actor considered alternative approaches and reasonably concluded that, under the circumstances, those approaches were either inadequate to address the identified risks of harm or would not have reduced the likelihood of interference with access, exchange, or use of EHI. For example, a tailored response to the existence of corrupted data would necessarily permit all uncorrupted EHI to continue to be accessed, used, and exchanged. This condition would not be met, for example, if an actor's policy imposed a blanket ban on the sharing of EHI with users of different technologies or with health care providers who are not part of a particular health system, HIE, or HIN.

Qualifying Individualized Finding

We recognize that some health care providers (such as small practices) may not have comprehensive and formal policies governing all aspects of EHI and patient safety. Additionally, even if an organizational policy exists, it may not anticipate all of the potential risks of harm that could arise in real-world clinical or production environments of health IT. In these circumstances, in lieu of demonstrating that a practice conformed to the actor's policies and that the policies met the conditions described above, the actor could justify the practice or practices directly by making a finding in each case, based on the particularized facts and circumstances, that the practice is necessary and no broader than necessary to mitigate the risk of harm. To do so, we propose that the actor would need to show that the practices were approved on a case-by-case basis by an individual with direct knowledge of the relevant facts and circumstances and who had relevant clinical, technical, or other appropriate expertise. Such an individual would need to reasonably conclude, on the basis of those particularized facts and circumstances and his/her expertise and best professional judgment, that the practice was necessary, and no broader than necessary, to mitigate the risk of harm to a patient or other persons.

We propose that a licensed health care professional's independent and individualized judgment about the safety of the actor's patients or other persons would be entitled to substantial deference under this proposed exception. So long as the clinician actually considered all of the relevant facts and determined that, under the particular circumstances, the practice was necessary to protect the safety of the clinician's patient or other person, we would not second-guess the clinician's judgment. To provide further clarity on this point, we provide the following illustration.

A clinician suspects that a patient is at risk of domestic abuse. The patient has recently visited the clinic for a pregnancy test, and tells the clinician that the potential father is not her current partner. The test returns a positive result. The clinician notes that in the patient's electronic health record, her partner has been given access to view her test results. The clinician, considering all factors for this particular situation and particular patient, and aware of the clinic's policy towards the restriction of electronic health information sharing, concludes that releasing this result electronically could place the patient at risk of harm. The clinician thus chooses not to release the test result electronically and plans to deliver the result to the patient in a safe manner. The exception would apply in this case because the clinician reasonably believes, based on the relationship with this particular patient and the clinician's best clinical judgment, that the restriction is

necessary to prevent harm to the patient.

We seek public comment on whether this proposed exception is appropriate and adequately balances the interest of promoting access, exchange, and use of EHI with legitimate concerns about the risk of harm to patients and others. In addition to any other relevant issues, we specifically request feedback on whether the exception is broad enough to prevent harm to patients and others and, if not, what additional risks we should address should we finalize this proposal; and whether there are additional safeguards the Secretary should adopt in order to prevent practices that attempt to undermine the policy goal of the exception. We also seek comment on whether there are customary practices (*e.g.,* standards of care) that advance patient safety concerns but which actors do not, as a matter of practice, record in documented policies, and which should be taken into account when assessing the reasonableness of a practice under this exception.

2. Promoting the Privacy of EHI

We propose to establish an exception to the information blocking provision for practices that are reasonable and necessary to protect the privacy of an individual's EHI, provided certain conditions are met. The exception and corresponding conditions are set forth in the proposed regulation text in § 171.202. We note that any practice engaged in to protect the privacy of an individual's EHI must be consistent with applicable laws related to health information privacy, including the HIPAA Privacy Rule as applicable, as well as with other applicable laws and regulations, such as the HITECH Act, 42 CFR part 2, and state laws. This exception to the information blocking provision does not alter an actor's obligation to comply with these and other applicable laws.

We believe this exception is necessary to support basic trust and confidence in health IT infrastructure. Without this exception, there would be a significant risk that actors would share EHI in inappropriate circumstances, such as when an individual has taken affirmative steps to request that the EHI not be shared, or when an actor has been unable to obtain reasonable assurances as to an individual's identity.

In contrast to the other exceptions defined in this proposed rule, this proposed exception has been structured with discrete ''sub-exceptions.'' An actor's practice must qualify for a sub-exception in order to be covered by this exception. The sub-exceptions have, to a large extent, been crafted to closely mirror privacy-protective practices that are recognized under state and federal privacy laws. In this way, the privacy sub-exceptions to the information blocking provision would recognize as reasonable and necessary practices that are engaged in by actors consistent with privacy laws, provided that certain conditions are met. We have proposed four sub-exceptions that address the following privacy protective practices: (1) Not providing access, exchange, or use of EHI when a state or federal law requires that a condition be satisfied before an actor provides access, exchange, or use of EHI, and the condition is not satisfied (proposed in § 171.202(b)); (2) not providing access, exchange, or use of EHI when the actor is a health IT developer of certified health IT that is not covered by the HIPAA Privacy Rule in respect to a practice (proposed in § 171.202(c)); (3) a covered entity, or a business associate on behalf of a covered entity, denying an individual's request for access to their electronic PHI in the circumstances provided in 45 CFR 164.524(a)(1), (2), or (3) (proposed at § 171.202(d)); and (4) not providing access, exchange, or use of EHI pursuant to an individual's request, in certain situations (proposed in § 171.202(e)). The rationale for each sub-exception is described in detail below.

An actor would need to satisfy at least one sub-exception in order that a purportedly privacy-protective practice that interferes with access, exchange, or use of EHI not be subject to the information blocking provision. Each sub-exception has conditions that must be met in order that an actor's practice qualifies for protection under the sub-exception.

Specific Terminology Used for the Purposes of This Proposed Exception

We note that this proposed exception and our discussion below uses certain terms that are defined by the HIPAA Rules [114] but that, for purposes of this exception, may have a broader meaning in the context of the information blocking provision and its implementing regulations as set forth in this Proposed Rule. In general, the terms ''access,'' ''exchange,'' and ''use'' have the meaning explained in section VIII.C.4.a of this preamble. However, in some instances we refer to ''use'' in the context of a disclosure or use of ePHI under the HIPAA Privacy Rule, in which case we have explicitly stated that the term ''use'' has the meaning defined in 45 CFR 160.103. Similarly, we refer in a few cases to an individual's right of access under 45 CFR 164.524, in which case the term ''access'' should be understood in that HIPAA Privacy Rule context. For purposes of section 3022 of the PHSA, however, the term ''access'' includes, but is broader than, an individual's access to their PHI as provided for by the HIPAA Privacy Rule (see section VIII.C.4.a of this preamble).

Finally, the term ''individual'' is defined by the HIPAA Rules at 45 CFR 160.103. Separately, under the information blocking enforcement provision, the term ''individual'' is used to refer to actors that are health IT developers of certified health IT, HINs, or HIEs, (*see* section 3022(b)(2)(A) of the PHSA). For purposes of this exception (and only this exception), we use neither of these definitions. Instead, the term ''individual'' encompasses any or all of the following: (1) An individual defined by 45 CFR 160.103; (2) a person who is the subject of EHI that is being accessed, exchanged or used; (3) a person who legally acts on behalf of an individual or person described in (1) or (2), including as a personal representative, in accordance with 45 CFR 164.502(g); or (4) a legal representative authorized to make health care decisions on behalf of a person or an executor or administrator who can act on behalf of the deceased's estate under state or other law.

We clarify that (2) varies from (1) because there could be individuals who could be the subject of EHI that is being accessed, exchanged, or used under (2), but who would not be the subject of PHI under (1). The purpose of (2) is to include EHI that would be accessed, exchanged or used by entities that are not subject to HIPAA (*e.g.,* non-covered entities and non-business associates). These entities could include, for example, health IT developers or data analytics companies that have access to EHI, but are not business associates.

We also clarify that (3) encompasses a person with *legal* authority to act on behalf of the individual, which includes a person who is a personal representative as defined under the HIPAA Privacy Rule. We included the component of *legal* authority to act in (3) because the HIPAA Privacy Rule gives rights to parents or legal guardians in certain circumstances where they are not the ''personal representative'' for their child(ren). For instance, a non-custodial parent who has requested a minor child's medical records under a court-ordered divorce decree may have legal authority to act on behalf of the

[114] 45 CFR part 160 and subparts A, C, and E of part 164.

child even if he or she is not the child's ''personal representative.'' Further, in limited circumstances and if permitted under state law, a family member may have *legal* authority to act on behalf of a patient to make health care decisions in emergency situations even if that family member may not be the ''legal representative'' or ''personal representative'' of the patient.

We have adopted this specialized usage to ensure that this privacy exception extends protection to information about, and respects the privacy preferences of, *all* individuals, not only those individuals whose EHI is protected as ePHI by HIPAA covered entities and business associates.

Interaction Between Information Blocking, the Exception for Promoting the Privacy of EHI, and the HIPAA Privacy Rule

Having consulted extensively with the HHS Office for Civil Rights (OCR), who enforce the HIPAA Privacy, Security and Breach Notification Rules, we have developed the information blocking provision to advance our shared goals of preventing information blocking for nefarious or self-interested purposes while maintaining and upholding existing privacy rights and protections for individuals. The proposed exception for promoting the privacy of EHI (also referred to as ''the privacy exception'') operates in a manner consistent with the framework of the HIPAA Privacy Rule. We designed these exceptions to ensure that individual privacy rights are not diminished as a consequence of the information blocking provision, and to ensure that the information blocking provision does not require the use or disclosure of EHI in a way that would not be permitted under the HIPAA Privacy Rule. Our intent is that the information blocking provision does not conflict with the HIPAA Privacy Rule. Indeed, the sub-exception proposed in § 171.202(d) reflects a policy judgment that an actor's denial of access to an individual consistent with the limited conditions for such denials that are described in the HIPAA Privacy Rule at 45 CFR 164.524(a)(1), (2), and (3) is reasonable under the circumstances. We believe this resolves any potential conflict between limitations on an individual's right of access under the HIPAA Privacy Rule and the information blocking provision.

We note that the information blocking provision may operate to require that actors provide access, exchange, or use of EHI in situations that HIPAA does not. This is because the HIPAA Privacy Rule permits, but does not require, covered entities to use and disclose ePHI in most circumstances. The information blocking provision, on the other hand, requires that an actor provide access to, exchange, or use of EHI unless they are prohibited from doing so under an existing law or are covered by one of the exceptions detailed in this preamble. To illustrate, the HIPAA Privacy Rule permits health care providers to exchange ePHI for treatment purposes, but does not require them to do so. Under the information blocking provision, unless an exception to information blocking applies, or the interference is required by law, a primary care provider would be required to exchange ePHI with a specialist who requests it to treat an individual who was a common patient of the provider and the specialist, even if the primary care provider offered patient care services in competition with the specialist's practice, or would usually refer its patients to another specialist due to an existing business relationship.

Promoting Patient Privacy Rights

As discussed above, the information blocking provision would not require that actors provide access, exchange, or use of EHI in a manner that is not permitted under the HIPAA Privacy Rule or other privacy laws. As such, the privacy-protective controls existing under HIPAA would not be weakened by the information blocking provision. Moreover, we have structured the privacy exception to ensure that actors can engage in reasonable and necessary practices that advance the privacy interests of individuals.

For example, we believe that, unless required by law, actors should not be compelled to share EHI against patients' wishes or without adequate safeguards out of a concern that restricting the access, exchange, or use of the EHI would constitute information blocking. This could seriously undermine patients' trust and confidence in the privacy of their EHI and diminish the willingness of patients, providers, and other entities to provide or maintain health information electronically in the first place. In addition, such outcomes would undermine and not advance the goals of the information blocking provision and be inconsistent with the broader policy goal of the Cures Act to facilitate trusted exchange of EHI. Trusted exchange requires not only that EHI be shared in accordance with applicable law, but also that it be shared in a manner that effectuates individuals' expressed privacy preferences. We note and discuss below that an individual's expressed privacy preferences will not be controlling in all cases. An actor will not be able to rely on an individual's expressed privacy preference in circumstances where the access, exchange, or use is required by law.

For these reasons, we propose that the proposed sub-exception in § 171.202(e) would generally permit an actor to give effect to individuals' expressed privacy preferences, including their desire not to permit access, exchange, or use of their EHI. For example, provided that corresponding conditions have been met, a health care provider could honor a patient's request not to share their EHI in circumstances in which the HIPAA Privacy Rule would permit (though not require) the provider to disclose the information, such as for treatment purposes. At the same time, however, we believe that the privacy exception must be tailored to ensure that protection of an individual's privacy is not used as a pretext for information blocking. Accordingly, we propose that this exception, which is discussed more fully below, would be subject to strict conditions.

Privacy Practices Required by Law

Because the information blocking provision excludes from the definition of information blocking practices that are required by law (section 3022(a)(1) of the PHSA), privacy-protective practices that are required by law do not implicate the information blocking provision and do not require coverage from an exception. For example, the HIPAA Privacy Rule requires that a covered entity must agree to the request of an individual to restrict disclosure of protected health information (PHI) about the individual to a health plan if the disclosure is for the purpose of carrying out payment or health care operations and not otherwise required by law and the PHI pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full.[115] If an individual made such a request and met all requirements of the HIPAA Privacy Rule, the actor would be *required by law* not to exchange the individual's EHI to a health plan. In this situation, the actor's interference with access, exchange, or use would not be information blocking and as such, the actor would not need to benefit from this exception.

Practices that are ''required by law'' can be distinguished from other practices that an actor engages in pursuant to a privacy law, but which are not ''required by law.'' Such privacy laws are typically framed in a way that

[115] 45 CFR 164.522(a)(1)(vi).

conditions the making of a ''disclosure'' on the satisfying of specific conditions, but does not expressly require that the actor engage in a practice that interferes with access, exchange, or use of EHI. For example, the HIPAA Privacy Rule provides that a covered entity *may* use or disclose PHI in certain circumstances where the individual concerned has authorized the disclosure.[116] The effect of this requirement is that the covered entity should not use or disclose the PHI in the absence of an individual's authorization. However, because the requirement does not prohibit the actor from exchanging the EHI in all circumstances, the actor would be at risk of engaging in a practice that was information blocking unless an exception applied. For this reason, we have included a sub-exception, addressed in § 171.202(b) and discussed below, that provides that an actor will not be engaging in information blocking if a state or federal privacy law imposes a precondition to the provision of access, exchange, or use, and that precondition has not been satisfied.

Sub-Exception To Proposed Privacy Exception: Precondition Not Satisfied

State and federal privacy laws that permit the disclosure of PHI often impose conditions that must be satisfied prior to a disclosure being made. We propose to establish a sub-exception to the information blocking provision that recognizes that an actor will not be engaging in information blocking if an actor does not provide access, exchange, or use of EHI because a necessary precondition required by law has not been satisfied. This exception will apply to all instances where an actor's ability to provide access, exchange, or use is ''controlled'' by a legal obligation to satisfy a condition, or multiple conditions, prior to providing that access, exchange, or use. To be covered by this exception, the actor must comply with conditions, which are discussed below.

The nature of the preconditions that an actor must satisfy in order to provide access, exchange, or use of EHI will depend on the privacy laws that regulate the actor. An actor that is regulated by a restrictive state privacy law may need to satisfy more conditions than an actor regulated by a less restrictive state privacy law, before providing access, exchange, or use. Similarly, certain state privacy laws may impose standards for meeting preconditions that are more rigorous than the laws in force elsewhere.

To illustrate how we propose this sub-exception would operate, we provide the following examples. We note that this list of examples is not exhaustive and that preconditions required by law that control access, exchange, or use of EHI that are not listed below would still qualify under this proposed sub-exception so long as all conditions are met.

- Certain federal and state laws require that a person provide consent before his or her EHI can be accessed, exchanged, or used for specific purposes. Although the HIPAA Privacy Rule does not have consent requirements for an individual (as that term is defined in the HIPAA Privacy Rule) when a covered entity or business associate is using or disclosing ePHI for treatment, payment or health care operations, some state laws and federal laws and regulations do require that a person's consent be obtained by the disclosing party/entity before disclosing certain health information. For example, for some sensitive health conditions such as HIV/AIDS, mental health, or genetic testing, state laws may impose a higher standard for disclosure of such information (*i.e.,* require consent) than is required under the HIPAA Privacy Rule. Additionally, under 42 CFR part 2, federally-assisted ''Part 2 programs'' generally are required to obtain a person's consent to disclose or re-disclose patient-identifying information related to the person's substance use disorder, such as treatment for addiction. The exception would operate to clarify an actor's compliance obligations in these situations. It would not be considered information blocking to refuse to provide access, exchange, or use of EHI if the actor has not received the person's consent, subject to conditions discussed herein.
- If an actor is required by law to obtain an individual's HIPAA authorization before providing access, exchange, or use of the individual's EHI, then the individual's refusal to provide an authorization would justify the actor's refusal to provide access, exchange, or use of EHI. The actor's refusal would, subject to conditions discussed herein, be protected under this exception.
- The HIPAA Privacy Rule, and many state privacy laws, authorize the disclosure of PHI in certain circumstances only once the identity and authority of the person requesting the information has been verified. We acknowledge that it is reasonable and necessary that actors take appropriate steps, consistent with federal and state laws, to ensure that EHI is not disclosed to the wrong person or to a person who is not authorized to receive it. Where an actor cannot verify the identity or authority of a person requesting access to EHI, and such verification is required by law before the actor can provide access, exchange, or use of the EHI, the actor's refusal to provide access, exchange, or use will, subject to the conditions discussed herein, be reasonable and necessary and will not be information blocking.
- Under the HIPAA Privacy Rule, a health care provider may share information with another health care provider for a quality improvement project if it has verified that the requesting entity has a relationship with the person whose information is being requested. Where the actor could not establish if the relationship existed, it would not be information blocking for the actor to refuse to provide access, exchange, or use, subject to the conditions discussed herein.

We seek comments generally on this proposed sub-exception. More specifically, we seek comment on how this proposed sub-exception would be exercised by actors in the context of state laws. We are aware that actors that operate across state lines or in multiple jurisdictions sometimes adopt organization-wide privacy practices that conform with the most restrictive privacy laws regulating their business. In order to ensure that the information blocking provision does not diminish the privacy rights of individuals being serviced by such actors, we are considering the inclusion of an accommodation in this sub-exception that would recognize an actor's observance of a legal precondition that the actor is required by law to satisfy in at least one state in which it operates. We believe this approach would be consistent with practices already in place for multi-state health care systems. For example, some states require specific consent requirements before exchanging sensitive health information such as a patient's mental health condition. As a result, the health care system will utilize one consent form for multi-jurisdiction purposes in order to meet various federal and state law requirements. However, in the event that we did adopt such an accommodation, we would also need to carefully consider how to ensure that before the use of the most stringent restriction is applied in all jurisdictions, the actor has provided all privacy protections afforded by that law across its entire business. This type of approach would ensure that an actor cannot take advantage of a more-restrictive privacy law for the benefit of this exception while not also fulfilling

[116] 45 CFR 164.508 (Uses and disclosures for which an authorization is required).

the privacy-protective obligations of the law being relied on. We seek comment on whether there is a need for ONC to adopt such an accommodation for actors operating in multiple states, and encourage commenters to identify any additional conditions that should attach to the provision of such an accommodation. We also request comment on our proposed approach to dealing with varying state privacy laws throughout this proposed sub-exception.

We also recognize that under the patchwork of state privacy laws, some states have enacted laws that more comprehensively identify the circumstance in which an individual or entity can and cannot provide access, exchange, or use of EHI. We are considering to what extent health care providers that are not regulated by the HIPAA Privacy Rule, and would rely instead on state laws for this sub-exception, would be able to benefit from this sub-exception when engaging in practices that interfere with access, exchange, or use of EHI for the purpose of promoting patient privacy. We seek comment on any challenges that may be encountered by health care providers that are not regulated as covered entities under the HIPAA Privacy Rule when seeking to take advantage of this proposed sub-exception. We also seek comment on whether there exists a class of health care provider that is not regulated by *any* federal or state privacy law that prescribes preconditions that must be satisfied in connection with the disclosure of EHI, and whether any such class of health care provider would benefit from a sub-exception similar to that proposed in § 171.202(c) for health IT developers of certified health IT.

Conditions To Be Met To Qualify for the Sub-Exception

In most circumstances, an actor would be in a position to influence whether a precondition is satisfied. For example, an actor could deprive a person of the opportunity to take some step that is a prerequisite for the exchange of their EHI, could assume the existence of a fact prejudicial to the granting of access without seeking to discover the truth or otherwise of the fact, or could make a determination that a precondition was not satisfied without properly informing itself of all relevant information. As such, we propose that this exception would be subject to conditions that ensure that the protection of an individual's privacy is not used as a pretext for information blocking.

We propose that an actor can qualify, in part, for this sub-exception by implementing and conforming to organizational policies and procedures that identify the criteria to be used by the actor and, as applicable, the steps that the actor will take, in order to satisfy the precondition. Most actors are covered entities or business associates for the purposes of the HIPAA Privacy Rule, and are already required to have policies and procedures and training programs in place that address how PHI and ePHI is used (as that term is defined in 45 CFR 160.103, as amended) and disclosed. As such, we expect that the overwhelming majority of actors will already be in a position to meet this condition, or would be able to meet this condition with modest additional effort. However, we acknowledge that some actors may not, for whatever reason, have privacy policies and practices in place, or may have implemented privacy policies and practices that do not sufficiently address the criteria to be used, and steps to be taken, to satisfy a precondition relied on by the actor. As such, we propose to provide an alternative basis on which to qualify, in part, for this sub-exception. We propose to permit actors to instead document, on a case-by-case basis, the criteria used by the actor to determine when the precondition will be satisfied, any criteria that were not met, and the reason why the criteria were not met. These alternative conditions, which are discussed in detail below, ensure that this sub-exception does not protect practices that are post hoc rationalizations used to justify improper practices, whilst also ensuring that actors do not face any pressure to disclose EHI in the situation where they do not have privacy policies and practices in place, or where their privacy policies and practices do not respond to the requirements of this condition.

Separately, we propose that if the precondition that an actor purports to have been satisfied relies on the provision of a consent or authorization from an individual, it is a condition of this sub-exception that the actor must have done all things reasonably necessary within its control to provide the individual with a meaningful opportunity to provide that consent or authorization.

We reiterate, again, that the information blocking provision does not require the provision of access, exchange, or use of EHI in a manner that would not be permitted under the HIPAA Privacy Rule.

Organizational Policies and Procedures

If an actor seeks to qualify for this sub-exception, in part, by implementing and conforming to organizational policies and procedures, such policies and procedures must be in writing, and specify the criteria to be used by the actor, and, if applicable, the steps that the actor will take, in order to satisfy the precondition relied on by the actor not to provide access, exchange, or use of EHI. It would not be sufficient for an actor to simply identify the existence of the precondition in their organizational policies and procedures.

We acknowledge that certain preconditions may be outside the direct control of the actor. For example, the requirement that an actor receive a valid authorization before releasing EHI in certain circumstances would be a precondition to be satisfied by the individual, and the actor may have little ability to influence the nature of the authorization that it receives. For preconditions of this nature, the actor's policies and procedures would only need to identify the criteria that the actor will apply and the steps that the actor will take to facilitate the satisfaction of the precondition, such as identifying the requirements for a valid authorization and the follow up steps (if any) to be taken in response to receipt of an authorization that does not meet those requirements. In contrast, where the satisfaction of a precondition relies solely on an actor, such as the ''minimum necessary'' determination made by HIPAA covered entities (or their business associates) when exchanging EHI that is ePHI, the actor's policies and procedures would need to particularize the steps that the actor will take in order to ensure that it satisfies the precondition. Where the precondition falls somewhere in between and relies on actions taken by both the actor and an individual, the actor's policies and procedures would need to address how the actor would do the things necessary within its control, which would include the steps it should take to facilitate all actions needed to be taken by an individual.

Take, for example, the situation where an actor needed to determine whether the subject individual had a relationship with a requesting entity as a precondition to exchanging EHI. The actor's policies and practices should, at minimum, identify the criteria to be applied, being the evidence that the actor would need in order to satisfy itself of the existence of a relationship, such as receipt of a Medicare or other insurance number, or other indicia of a relationship such as the establishment of a doctor-patient relationship.

An actor would only be eligible to benefit from this sub-exception if it has followed its processes and policies. Continuing the above example, an actor

that chose not to provide access to EHI on the basis that insufficient evidence had been provided to establish the existence of the relationship, would need to show that its decision was based on the applicable criteria specified in the actor's policy and practices.

Using a different example, and as discussed above, the HIPAA Privacy Rule generally requires covered entities (and their business associates) to take reasonable steps to limit the use or disclosure of, and requests for, PHI to the minimum necessary to accomplish the intended purpose.[117] Satisfying the ''minimum necessary'' requirement is a precondition to be met under the HIPAA Privacy Rule before an actor exchanges ePHI for many purposes. The determination of what constitutes the ''minimum necessary'' is a fact based judgment made by an actor. To allow covered entities the flexibility to address their unique circumstances, the HIPAA Privacy Rule requires covered entities (and their business associates) to make their own assessment of what ePHI is reasonably necessary for a particular purpose, given the characteristics of their business and workforce. To qualify for this proposed sub-exception, the actor's privacy policies and procedures would need to identify criteria for making a ''minimum necessary'' determination for both routine and non-routine disclosures and requests, including identifying the circumstances under which disclosing the entire medical record is reasonably necessary. For actors that are covered entities or business associates, the development of policies and procedures for the making of minimum necessary determinations for requesting, using and disclosing PHI is already a requirement of the HIPAA Privacy Rule, so we expect that actors will already have such policies and procedures in place. If an actor implemented its organizational policies and procedures for making ''minimum necessary'' determinations consistent with the HIPAA Privacy Rule, and otherwise met the other conditions of this exception, a decision to exchange the minimum necessary information but less information than requested by another entity would satisfy this sub-exception and not be considered information blocking.

Finally, an actor's policies and procedures must be implemented. This ensures that an actor can only satisfy this condition by reference to privacy policies and practices that individuals in fact benefit from, and not by policies and procedures that have been documented but not applied. Proper implementation would involve making the policies and processes available to all decision makers, and facilitating workforce and contractor understanding and consistent implementation of the actor's policies and procedures such as by providing training. This condition ensures that this sub-exception does not protect practices that are post hoc rationalizations used to justify improper practices.

As discussed above, to the extent existing state and federal laws apply to a given actor, we expect an actor to already have procedures in place to address those legal requirements. Indeed, the HIPAA Privacy Rule requires that covered entities have policies and procedures and training programs in place that address how PHI and ePHI are used (as those terms are defined in 45 CFR 160.103) and disclosed. Moreover, this exception is only enlivened when an actor asserts that its conduct was carried out to satisfy a precondition, and we expect that such conduct should be considered and deliberate.

We seek comment on this proposed condition generally, and specifically, on whether an actor's organizational policies and procedures provide a sufficiently robust and reliable basis for evaluating the bona fides, reasonableness, and necessity of practices engaged in to satisfy preconditions required by state or federal privacy laws.

Documenting Criteria and Rationale

If an actor's practice does not conform to an actor's organizational policies and procedures as required by § 171.202(b)(1), we propose that that an actor can seek to qualify for this sub-exception, in part, by documenting how it reached its decision that it would not provide access, use, or exchange of EHI on the basis that a precondition had not been satisfied. Such documentation must be created on a case-by-case basis. An actor will not satisfy this condition if, for instance, it sought to document a general practice that it had applied to all instances where the precondition had not been satisfied. Rather, the record created by the actor must address the specific circumstances of the specific practice (or interference) at issue.

The record created by the actor must identify the criteria used by the actor to determine when the precondition is satisfied. That is, it must identify the objective criteria that the actor applied to determine whether the precondition had been satisfied. Consistent with the condition to this sub-exception that the practice must be tailored to the privacy interest at issue (discussed below), those criteria would need to be directly relevant to satisfying the precondition. For example, if the precondition at issue was the provision of a valid HIPAA authorization, the actor's documented record should reflect, at minimum, that the authorization would need to meet each of the requirements specified for a valid authorization at 45 CFR 164.508(c). The record would then need to document the criteria that had not been met, and the reason so. Continuing the example, the actor could record that the authorization did not contain the name or other specific identification of the person making the request because the authorization only disclosed the person's first initial rather than first name, and the actor had records about multiple people with that same initial and last name.

We believe that this condition will provide the transparency necessary to demonstrate whether the actor has satisfied the conditions applicable to this exception. Moreover, it will ensure that a decision to not provide access, exchange, or use of EHI is considered and deliberate, and therefore reasonable and necessary.

We seek comment on this proposed condition.

Meaningful Opportunity To Provide Consent or Authorization

If the precondition that an actor purports to have satisfied relies on the provision of a consent or authorization from an individual, it is a condition of this sub-exception that the actor must have done all things reasonably necessary within its control to provide the individual with a meaningful opportunity to provide that consent or authorization. This condition will be relevant when, for example, a state privacy law or the HIPAA Privacy Rule requires an individual to provide their consent and/or HIPAA authorization before identifiable information can be accessed, exchanged, or used for specific purposes. For instance, a state law may require that an individual provide consent before a hospital can share her treatment information electronically with another treating health care provider. Under this scenario, the hospital's refusal to exchange the EHI in the absence of the individual's consent would be reasonable and necessary and would not be information blocking, so long as the hospital had provided the individual with a meaningful opportunity to provide that consent and where the criteria and other conditions of this proposed exception were met.

[117] 45 CFR 164.502(b).

In the context of the provision of consent, a meaningful opportunity would ordinarily require that an actor provide the individual with a legally compliant consent form; make a reasonable effort to inform an individual that she has the right to consent to the disclosure of her EHI; and provide the individual with sufficient information and educational material (commensurate with the circumstances of the disclosure). It would be best practice for an actor to also inform the individual about the revocability of any consent given, if and as provided in the relevant state or federal privacy law, and the actor's processes for acting on any revocation.

We are considering addressing this condition in further detail, whether by way of additional guidance or in regulation text. To this end, we seek comments regarding what actions an actor should take, within the actor's control, to provide an individual with a meaningful opportunity to provide a required consent or authorization, and whether different expectations should arise in the context of a consent versus a HIPAA authorization. For example, commenters may wish to provide comment on the actions to be taken to ensure that an individual has a meaningful opportunity to satisfy a precondition that the individual provide a HIPAA authorization. Specifically, in the context of a requirement that the authorization be signed, what effort should be expected from actors in seeking signatures from: (i) Persons acting for the patient where the patient is unable to sign a form; (ii) former patients whose EHI is being requested from third parties; or (iii) patients that are not in a facility, such as patients of individual physicians?

We clarify that after providing the individual with a meaningful opportunity to consent or provide authorization, we believe that it is the individual's responsibility to complete any required documentation before an actor is able to access, exchange, or use the individual's EHI. We do not expect the actor to ''chase'' the individual despite using its best efforts provide the individual with an opportunity to sign a consent or authorization form. So long as the actor has provided the individual with a meaningful opportunity to consent, the actor will have fulfilled this aspect of the eligibility requirements of this sub-exception.

Separately, to qualify for this sub-exception, to the extent that the precondition at issue was the provision of a consent or authorization by an individual, the actor must not have improperly encouraged or induced the individual to not provide the consent or authorization. This does not mean that the hospital cannot inform an individual about the advantages and disadvantages of exchanging EHI and any associated risks, so long as the information communicated is accurate and legitimate. However, an actor would not meet this condition in the event that it misled an individual about the nature of the consent to be provided, dissuaded individuals from providing consent in respect of disclosures to the actor's competitors, or imposed onerous requirements to effectuate consent that were unnecessary and not required by law.

We seek comment on whether the proposed condition requiring the provision of a meaningful opportunity and prohibiting improper encouragement or inducement should apply to preconditions beyond the precondition that an individual provide consent or authorization. We seek comment on whether the conditions specified for this sub-exception, when taken in total, are sufficiently particularized and sufficiently strict to ensure that actors that are in a position to influence whether a precondition is satisfied will not be able to take advantage of this sub-exception and seek protection for practices that do not promote the privacy of EHI. We also seek comment on whether we should adopt a more tailored approach to conditioning the availability of this exception. For example, we are considering whether different conditions should apply depending on: (i) The nature of the EHI at issue; (ii) the circumstances in which the EHI is being access, exchanged, or used; (iii) the interest being protected by the precondition; or (iv) the nature of the precondition to be satisfied. Commenters are encouraged to identify scenarios in which the application of the conditions applicable to this sub-exception, as proposed, give rise to unnecessary burden, or would require activities that do not advance the dual policy interests of preventing information blocking and promoting privacy and security.

Practice Must Be Tailored to the Specific Privacy Risk or Interest Being Addressed

To qualify for this sub-exception, an actor's privacy-protective practice must be tailored to the specific privacy risks that the practice actually addresses. This condition necessarily presupposes that an actor has carefully evaluated the privacy requirements imposed on the actor, the privacy interests to be managed by the actor, and has developed a considered response that is tailored to protecting and promoting the privacy of EHI. For example, the HIPAA Privacy Rule at 45 CFR 164.514(h) requires that, in certain circumstances, the disclosure of PHI is only authorized once the identity and authority of the person requesting the information has been verified. The privacy issue to be addressed in this instance is the risk that PHI will be disclosed to the wrong individual, or an unauthorized person. If an actor chooses not to provide access, exchange, or use of EHI on the basis that the actor's identity verification requirements have not been satisfied, the actor's practice must be tailored to the specific privacy risks at issue. This would require that the actor ensure that it does not impose identity verification requirements that are unreasonably onerous under the circumstances.

To illustrate, a policy where a driver's license was the only accepted government-issued form of identification would not be a practice that is tailored to the privacy risk at issue because the provider's preference for one form of government-issued identification over another does not meaningfully manage the privacy risk. Similarly, it may be unreasonable for an actor to require the production of documentation demonstrating the parent-child relationship unless the actor was in possession of information that suggested that an adult might not have authority to be the child's legal representative. To do otherwise would be to apply an onerous requirement in all instances of parent-child relationships, which is insufficiently tailored to the privacy risk being managed. Finally, it may be unreasonable for an actor to insist that the individual produce original identification if the individual was able to furnish a scanned copy of their form of identification that the actor could reasonably rely on.

For the purposes of this sub-exception, we clarify that engaging in an interference on the basis that a precondition has not been satisfied would be a practice that addresses a privacy risk or interest, and so tailoring that interference to satisfy a precondition can satisfy this condition. Controls on access, exchange, or use arising under privacy laws serve a privacy interest and so this condition will be met so long as the actor's practice is tailored to the risk or interest being addressed.

We seek comment on this proposed condition.

Practice Must Be Implemented in a Consistent and Non-Discriminatory Manner

We propose that in order for a practice to qualify for this sub-exception, the practice must be implemented in a consistent and non-discriminatory manner. This condition would provide basic assurance that the purported privacy practice is directly related to a specific privacy risk and is not being used to interfere with access, exchange, or use of EHI for other purposes to which this exception does not apply.

This condition requires that the actor's privacy-protective practices must be based on objective criteria that apply uniformly for all substantially similar privacy risks. An actor could not, for example, implement an organizational privacy policy that imposed unreasonably onerous requirements on a certain class of individuals or entities without a legitimate justification for doing so. For example, an actor that offered a patient-facing software application (app) would not be able to benefit from this exception if it refused to exchange EHI with a competitor app on the basis of an individual's failure to meet onerous authorization requirements that applied only to health information exchange with the competitor app and did not apply to, for example, the exchange of EHI with health care providers. This condition provides basic assurance that the purported privacy-protective practice is not being used to interfere with access, exchange, or use of EHI for other purposes to which this proposed exception does not apply.

We request comment on this proposed condition.

Sub-Exception to Proposed Privacy Exception: Health IT Developer of Certified Health IT Not Covered by HIPAA

The sub-exception proposed in § 171.202(b) recognizes as reasonable and necessary the activities engaged in by actors consistent with the controls placed on access, exchange, or use of EHI by federal and state privacy laws. Importantly, that sub-exception is limited to actors that are subject to those federal and state privacy laws; an actor that is not regulated by HIPAA or a state privacy law cannot benefit from the exception proposed in § 171.202(b).

We propose to establish a sub-exception to the information blocking provision that would apply to actors that are health IT developers of certified health IT but not regulated by the HIPAA Privacy Rule in respect to the operation of the actor's health IT product or service (referred to hereafter as ''non-covered actors''). We expect that the class of actors to which this proposed sub-exception applies will be very small. The vast majority of health IT developers of certified health IT operate as business associates to health care providers or health plans, are regulated by the HIPAA Privacy Rule, and will be able to benefit from the exception proposed in § 171.202(b) to the extent that the HIPAA Privacy Rule (or applicable state privacy law) imposes preconditions to the provision of access, exchange, or use of EHI. However, we recognize that direct-to-consumer health IT products and services are a growing sector of the health IT market. This class of health IT is often not regulated by the HIPAA Privacy Rule, but could be certified under the Program. We note that the privacy practices of consumer-facing health IT products and services are typically regulated by the Federal Trade Commission Act (FTC Act). However, the FTC Act applies to acts and practices that are unfair and deceptive (15 U.S.C. 45(a)(1)), and does not prescribe privacy requirements to be adopted or followed that can be leveraged for the purpose of recognizing reasonable and necessary privacy-protective practices in this proposed rule.[118]

As discussed in section VIII.C.2.b, where a health IT developer of certified health IT offers a health IT product or service not regulated by the HIPAA Privacy Rule, such product or service is subject to the information blocking provision. We want to ensure that non-covered actors that engage in reasonable and necessary privacy-protective practices that interfere with the access, exchange, or use of EHI can seek coverage under this proposed sub-exception. As such, we propose that a non-covered actor will not engage in information blocking if the actor does not provide access, exchange, or use of EHI where the practice implements a process that is described in the actor's organizational privacy policy and has been disclosed to any individual or entity that uses the actor's health IT. This proposed sub-exception is proposed in § 171.202(c).

As a threshold requirement of this sub-exception, the actor's practice of interfering with access, exchange, or use of EHI must comply with any applicable state or federal privacy laws. While we have developed this sub-exception for the express purpose of addressing privacy-protective practices that are not regulated by the HIPAA Privacy Rule, we acknowledge that there may be other privacy laws implicated by the practice in question. If the actor's practice contravenes a state or federal privacy law, but otherwise satisfies this proposed sub-exception, the actor would not be entitled to benefit from this sub-exception.

Practice Must Implement Privacy Policy

In order to qualify for this sub-exception, the practice engaged in by the non-covered actor—the interference with access, exchange, or use of EHI—must also implement a process described in the actor's organizational privacy policy. This requires that a non-covered actor must have documented in detail in its organizational privacy policy the processes and procedures that the actor will use to determine when the actor will not provide access, exchange, or use of EHI. For example, a non-covered actor that proposed to require the provision of written consent for the use or disclosure of EHI would need to describe in its organizational privacy policy the processes and procedures to be utilized by the actor to implement that privacy-protective practice in order that the practice be considered reasonable and necessary and qualify for this sub- exception. A privacy policy that was prepared at a high level—for example, that simply stated that written consent was required—would not qualify. To build on this example, a non-covered actor's consent policy would need to describe the specific requirements that are imposed on individuals when giving consent, together with the processes and procedures to be followed by the non-covered actor to ensure that the individual has a meaningful choice over whether to consent. Compliance with this condition ensures that this sub-exception recognizes only legitimate practices that have been tailored to the privacy needs of the individuals that use the non-covered actor's health IT, and does not recognize practices that are a pretext or after-the-fact rationalization for actions that interfere with access, exchange, or use of EHI.

It necessarily follows that the non-covered actor's practice must implement its documented organizational privacy policy. For example, if a non-covered actor chose not to provide access, exchange, or use of EHI on the basis that it could not verify the identity of the individual requesting the EHI, the non-covered actor would need to be able to demonstrate that it implemented the

[118] *See* HHS, *Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA, https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf.*

part of its organizational privacy policy that dealt with identity verification. Practices that diverge from an actor's documented policies or practices, or which are not addressed in an actor's organizational privacy policy, would not qualify for this proposed sub-exception.

Practice Must Have Been Disclosed to Users

A non-covered actor that seeks to benefit from this proposed sub-exception must also ensure that it has previously disclosed the privacy-protective practice to the individuals and entities that use, or will use, the health IT. These users are affected by the practices engaged in by a non-covered actor but may otherwise have no visibility of the non-covered actor's approach to protecting the privacy of EHI. We expect that non-covered actors will seek to satisfy this condition by using a privacy notice.[119] We emphasize that the disclosure must be meaningful. In assessing whether a non-covered actor's disclosure was meaningful, regard will be paid to whether the disclosure was in plain language and conspicuous, including whether the disclosure was located in a place, and presented in a manner, that is accessible and obvious to the individuals and entities that use, or will use, the health IT.

To qualify for this sub-exception, a non-covered actor would not be required to disclose its organizational privacy policy to its customers or to the public generally. Rather, the non-covered actor need only describe, with sufficient detail and precision to be readily understood by users of the non-covered actor's health IT, the privacy-protective practices that the non-covered actor has adopted and will observe. This is necessary because a non-covered actor that is not subject to prescribed privacy standards in connection with the provision of health IT will have significant flexibility in the privacy-protective practices that it adopts. If an actor is not required to inform the individuals and entities that use, or will use, the health IT, about the privacy- protective practices that it will implement in its product, or when providing its service, there is a risk that this proposed sub-exception will give deference to policies and processes that are post hoc rationalizations used to justify improper practices. This condition also serves as a check on the nature of the interferences that a non-covered actor writes into its organizational privacy policies; transparency will help to ensure that a non-covered actor takes a balanced approach to protecting privacy interests on one hand, and pursuing business interests that might be inconsistent with the information blocking provision, on the other hand. We hope that this requirement will foster a quasi-market based measure of when a privacy-protective practice is ''reasonable and necessary,'' and ensure that any departure made by a non-covered actor from privacy practices that are recognized by state or federal law is transparent and open.

It will be a matter for non-covered actors to determine the most appropriate way to communicate its privacy practices to users. We believe that it would be reasonable that non- covered actors would, at minimum, post their privacy notices, or otherwise describe their privacy-protective practices, on their websites.

Practice Must Be Tailored to Privacy Risk and Implemented in a Non-Discriminatory Manner

Finally, we propose that in order for a practice to qualify for this sub-exception, an actor's practice must be tailored to the specific privacy risks that the practice actually addresses, and must be implemented in a consistent and non-discriminatory manner. These conditions also apply to the exception proposed in § 171.202(b), and the discussion above addressing these conditions in connection with § 171.202(b) applies to this proposed exception in § 171.202(c). We refer readers to the above discussion and invite comments on these proposed conditions.

We seek comment on this proposed sub-exception generally. Specifically, we seek comment on whether HIEs or HINs would benefit from a similar sub-exception. We also seek comment on whether the conditions applicable to this sub-exception are sufficient to ensure that non-covered actors cannot take advantage of this exception by engaging in practices that are inconsistent with the promotion of individual privacy. We also seek comment on the level of detail that non-covered actors should be required to use when describing their privacy practices and processes to user of health IT.

Sub-Exception to Proposed Privacy Exception: Denial of an Individual's Request for Their Electronic Protected Health Information in the Circumstances Provided in 45 CFR 164.524(a)(1), (2), and (3)

We propose a limited sub-exception to the information blocking provision that would permit a covered entity or business associate to deny an individual's request for access to their PHI in the circumstances provided under 45 CFR 164.524(a)(1), (2), and (3). We believe this exception would avoid a potential conflict between the HIPAA Privacy Rule and the information blocking provision. Specifically, the HIPAA Privacy Rule contemplates circumstances under which covered entities, and in some instances business associates, may deny an individual access to PHI and distinguishes those grounds for denial which are reviewable from those which are not. This exception applies to both the ''unreviewable grounds'' and ''reviewable grounds'' of access. The ''unreviewable grounds'' for denial for individuals include situations involving: (1) Certain requests that are made by inmates of correctional institutions; (2) information created or obtained during research that includes treatment, if certain conditions are met; (3) denials permitted by the Privacy Act; and (4) information obtained from non-health care providers pursuant to promises of confidentiality. In addition, two categories of information are expressly excluded from the individual right of access: (1) Psychotherapy notes, which are the personal notes of a mental health care provider documenting or analyzing the contents of a counseling session that are maintained separate from the rest of the patient's medical record (*see* 45 CFR 164.524(a)(1)); and (2) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding (*see* 45 CFR 164.501).

The ''reviewable grounds'' of access as described in § 164.524(a)(3), which provides that a covered entity may deny access provided that the individual is given a right to have such denials reviewed under certain circumstances. One such circumstance is when a licensed health care professional, in the exercise of professional judgment, determines that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person. In addition, if access is denied, then the individual has the right to have the denial reviewed by a

[119] ONC has provided a Model Privacy Notice (MPN) that is a voluntary, openly available resource designed to help developers clearly convey information about their privacy and security policies to their users. Similar to the FDA Nutrition Facts Label, the MPN provides a snapshot of a company's existing privacy practices encouraging transparency and helping consumers make informed choices when selecting products. The MPN does not mandate specific policies or substitute for more comprehensive or detailed privacy policies. See *https://www.healthit.gov/topic/privacy-security-and-hipaa/model-privacy-notice-mpn.*

licensed health professional who is to act as a reviewing official and did not participate in the original decision to deny access (*see generally* 45 CFR 164.524(a)(3)).

We propose that if an actor who is a covered entity or business associate denies an individual's request for access to their PHI on the basis of these unreviewable and reviewable grounds, and provided the denial of access complies with the requirements of the HIPAA Privacy Rule in each case, then the actor would qualify for this exception and these practices would not constitute information blocking.

The following example illustrates this proposed sub-exception. An individual is a patient of a psychiatrist who is a HIPAA covered entity. The patient has requested all of his electronic health files from the psychiatrist. The psychiatrist maintains separately from the electronic health record a file containing psychotherapy notes regarding the patient. The psychiatrist grants access to the patient by providing a copy of the information in his electronic health record, but does not provide the patient's psychotherapy notes. Under this example, the psychiatrist would meet the requirements of this proposed exception since the HIPAA Privacy Rule provides that covered entities can deny individuals access to their psychotherapy notes and provides that this is an unreviewable grounds for denial.

We seek comment on this proposed sub-exception.

Sub-Exception to Proposed Privacy Exception: Respecting an Individual's Request Not To Share Information

We propose to establish an exception to the information blocking provision that would, in certain circumstances, permit an actor not to provide access, exchange, or use of EHI if an individual has specifically requested that the actor not do so. This sub-exception is proposed in § 171.202(e). We believe this sub-exception is necessary to ensure that actors are confident that they can respect individuals' privacy choices without engaging in information blocking, and to promote public confidence in the health IT infrastructure by effectuating patients' preference about how and under what circumstances their EHI will be accessed, exchanged, and used. We recognize that individuals may have concerns about permitting their EHI to be accessed, exchanged, or used electronically under certain circumstances. As a matter of public policy, we think that these privacy concerns, if expressed by an individual and agreed to by an actor, would be reasonable and necessary, and an actor's conduct in abiding by its agreement would, if all conditions are met, be an exception to the information blocking provision.

This proposed sub-exception would not apply under circumstances where an actor interferes with a use or disclosure of EHI that is required by law, including when EHI is required by the Secretary to enforce HIPAA under 45 CFR 164.502(a)(2)(ii) and 45 CFR 164.502(a)(4)(i). Stated differently, this sub-exception would not operate to permit an actor to refuse to provide access, exchange, or use of EHI when that access, exchange, or use is required by law. This sub-exception recognizes and supports the public policy objective of the HIPAA Privacy Rule, which identifies uses and disclosures of EHI for which the public interest in the disclosure of the individual's information outweighs the individual's interests in controlling the information.

This sub-exception would permit an actor not to share EHI if the following conditions are met: (1) The individual made the request to the actor not to have his or her EHI accessed, exchanged, or used; (2) the individual's request was initiated by the individual without any improper encouragement or inducement by the actor; and (3) the actor or its agent documents the request within a reasonable time period.

To qualify for this sub-exception, the request that the individual's EHI not be accessed, exchanged, or used must come from the individual. Moreover, the individual must have made the request independently and without any improper encouragement or inducement by the actor. For example, it would be improper to encourage individuals not to share information with unaffiliated providers on the basis of generalized or speculative risks of unauthorized disclosure. On the other hand, if the actor was aware of a specific privacy or security risk, it would not be improper to inform individuals of that risk. Likewise, an actor would be permitted to provide an individual with general information about her privacy rights and options, including for example, the option to not provide consent, provided the information is presented accurately, does not omit important information, and is not presented in a way that is likely to improperly influence the individual's decision about how to exercise their rights.

If an individual submits a request to an actor not to disclose her EHI, and the actor agrees with and documents the request, the request would be valid for purposes of this sub-exception unless and until it is subsequently revoked by the individual. We believe this approach would minimize compliance burdens for actors while also respecting individuals' requests. We propose that once the individual makes the request, she should not, subject to the requirements of applicable federal or state laws and regulations, have to continually reiterate her privacy preferences, such as having to re-submit a request every year. Likewise, we propose that once the actor has documented an individual's request, the actor should not have to repeatedly reconfirm and re-document the request. We seek comment, however, regarding whether this approach is too permissive and could result in unintended consequences. We also seek comment on this proposed sub-exception generally, including on effective ways for an individual to revoke his or her privacy request for purposes of this sub-exception.

We also propose that in order for a practice to qualify for this sub-exception, an actor's practice must be implemented in a consistent and non-discriminatory manner. This condition would provide basic assurance that the purported privacy practice is directly related to the risk of disclosing EHI contrary to the wishes of an individual, and is not being used to interfere with access, exchange, or use of EHI for other purposes to which this exception does not apply. This condition requires that the actor's privacy-protective practice must be based on objective criteria that apply uniformly for all substantially similar privacy risks.

We note that under the HIPAA Privacy Rule, individuals have the right to request restrictions on how a covered entity will use (as that term is defined in 45 CFR160.103) and disclose PHI about them for treatment, payment, and health care operations pursuant to 45 CFR 164.522(a)(1). Under § 164.522(a), a covered entity is not required to agree to an individual's request for a restriction (other than in the case of a disclosure to a health plan under § 164.522(a)(1)(vi)), but is bound by any restrictions to which it agrees.

We wish to clarify that, for the purposes of this proposed sub-exception, the actor may give effect to an individual's request not to have an actor disclose EHI even if state or federal laws would allow the actor not to follow the individual's request. This is consistent with our position that, absent improper encouragement or inducement, and subject to appropriate conditions, it should not be considered information blocking to give effect to

patients' individual preferences about how their EHI will be shared or not. As an illustration, if an individual requests that her EHI not be accessed, exchanged, or used by a physician to help train new staff at a hospital, the physician may agree not to use the individual's EHI for this purpose despite the fact it would not be required by law to agree to such a restriction. Provided the physician has not encouraged or induced the individual to make this request, this sub-exception would apply to the physician's refusal to disclose the information to staff for training purposes.

We seek comments on this sub-exception generally. Specifically, we seek comment on what would be considered a reasonable time frame for documentation. In addition, we also seek comment on how this sub-exception would affect public health disclosures and health care research, if an actor did not share a patient's EHI due to a privacy preference, including any effects on preventing or controlling diseases, injury, or disability, and the reporting of disease, injury, and vital events such as births or deaths, and the conduct of public health surveillance and health care research.

3. Promoting the Security of EHI

We propose to establish an exception to the information blocking provision that would permit actors to engage in practices that are reasonable and necessary to promote the security of EHI, subject to certain conditions. Without this exception, actors may be reluctant to implement security measures or engage in other activities that are reasonable and necessary for safeguarding the confidentiality, integrity, and availability of EHI. This could undermine the ultimate goals of the information blocking provision by discouraging best practice security protocols and diminishing the reliability of the health IT ecosystem.

Robust security protections are critical to promoting patients' and other stakeholders' trust and confidence that EHI will be collected, used, and shared in a manner that protects individuals' privacy and complies with applicable legal requirements. Public confidence in the security of their EHI has been challenged, however, by the growing incidence of cyber-attacks in the health care sector. More than ever, health care providers, health IT developers, HIEs and HINs must be vigilant to mitigate security risks and implement appropriate safeguards to secure the EHI they collect, maintain, access, use, and exchange.

The Cures Act directs the National Coordinator, in consultation with the HHS Office for Civil Rights (OCR), to issue guidance on common ''security barriers'' that prevent the trusted exchange of EHI (section 3022(c)(2) of the PHSA). However, the Cures Act also seeks to promote the security of EHI, which it defines as an element of interoperability (section 3000(9)(A) of the PHSA) and a target area for the policy development to be undertaken by the Health Information Technology Advisory Committee (section 3002(b)(2)(B)(ii) of the PHSA). The inclusion of these provisions promote broader access, exchange, and use of EHI while at the same time continuing to promote the confidentiality, integrity, and availability of EHI through security practices that are appropriate and tailored to identified vulnerabilities and risks.

To qualify for this exception, we propose that an actor's conduct must satisfy threshold conditions. As discussed in detail below, the particular security-related practice must be directly related to safeguarding the confidentiality, integrity, and availability of EHI, implemented consistently and in a non-discriminatory manner, and tailored to identified security risks.

While the importance of security practices cannot be overstated, this proposed exception would not apply to *all* practices that purport to secure EHI. Rather, this exception will only be available when the actor's security-based practice satisfies the conditions applicable to this exception. We do not believe it would be appropriate to prescribe a ''maximum'' level of security or to dictate a one-size-fits-all approach for all actors that may not be appropriate in all circumstances and may not accommodate new threats, countermeasures, and best practices in a rapidly changing security landscape. Indeed, security infrastructure varies from organization to organization, and there exist diverse approaches and technology solutions to managing security risks. We do not intend for this proposed exception to dictate a specific security approach when an actor's security posture must be agile and its practices iterative. Moreover, effective security best practices focus on the mitigation and remediation of risks to a reasonable and acceptable level, and not the elimination of all vulnerabilities, so organizations should have the flexibility to assess what vulnerabilities to address and how best to address them while ensuring the confidentiality, integrity, and availability of EHI.

As such, we propose that actors would be able to satisfy this exception through practices that implement either security policies and practices developed by the actor, or case-by-case determinations made by the actor. Whether a security-motivated practice meets this exception would be determined on a case-by-case basis using a fact-based analysis of the conditions set forth below. This approach offers the most appropriate framework for analyzing security practices, which are necessarily driven by and must be tailored to actors' individual circumstances.

We wish to emphasize that the security-based practices implemented by a single physician office with limited technology resources, for example, will be different to those implemented by a large health system, and that this difference does not affect an actor's ability to qualify for this exception. The fact-based approach we propose will allow each actor to implement policies, procedures, and technologies that are appropriate for its particular size, organizational structure, and risks to individuals' EHI.

A fact-based analysis also aligns with the HIPAA Security Rule [120] concerning the security of ePHI. The HIPAA Security Rule does not dictate the security measures that a covered entity or business associate must implement, but instead requires the entity to develop security practices and implement administrative, physical, and technical safeguards that take into account the entity's size, complexity, and capabilities; technical, hardware, and software infrastructure; the costs of security measures; and the likelihood and possible impact of potential risks to ePHI. Under the HIPAA Security Rule, covered entities and business associates are required to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI held by the covered entity or business associate. Once covered entities and business associates have completed the risk assessment, they must take security measures sufficient to reduce identified risks and vulnerabilities to reasonable and appropriate levels (45 CFR 164.308(a)(1)(ii)). We note, however, that while our approach is consistent with the regulation of security practices under the HIPAA Security Rule, the fact that a practice complies with the HIPAA Security Rule does not establish that it

[120] The HIPAA Security Rule is located at 45 CFR part 160 and Subparts A and C of Part 164 and 68 FR 8333.

meets the conditions of this proposed exception to the information blocking provision. The HIPAA Security Rule and this proposed exception have different focuses. The HIPAA Security Rule establishes a baseline by requiring certain entities to ensure the confidentiality, integrity, and availability of ePHI by implementing security measures, among other safeguards, that the entities determine are sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level. In contrast, the purpose of this exception to the information blocking provision is to provide flexibility for reasonable and necessary security practices while screening out practices that purport to promote the security of EHI but that are unreasonably broad, onerous on those seeking access to the EHI, are not applied consistently across/within an organization, or otherwise may unreasonably interfere with access, exchange, or use of EHI.

We propose the following conditions that must be met for an activity or practice to qualify for this exception.

The Practice Must Be Directly Related To Safeguarding the Confidentiality, Integrity, and Availability of EHI

As a threshold condition, the proposed exception would not apply to any practices that are not directly related to safeguarding the security of EHI. In assessing the practice, we would consider whether and to what extent the practice directly addressed specific security risks or concerns. We would also consider whether the practice served any other purposes and, if so, whether those purposes were merely incidental to the overriding security purpose or provided an objectively distinct, non-security-related rationale for engaging in the practice.

We note that it should not be particularly difficult or onerous for an actor to demonstrate, as contemplated above, that its practice was directly related to a specific security risk or concern. For example, the actor may show that the practice was a direct response to a known security incident or threat; or that the practice directly related to the need to verify a person's identity before granting access to EHI; or that the practice was directly related to ensuring the integrity of EHI.

The salient issue under this condition, therefore, would be whether the security practice was actually necessary and directly related to safeguarding EHI. To that end, we would consider the actor's purported basis for adopting the particular security practice, which could be evidenced by the actor's organizational security policy, risk assessments, and other relevant documentation, which most actors are already required to develop pursuant to requirements under the HIPAA Rules.[121] However, we propose that the documentation of an actor's decision-making would not necessarily be dispositive. For example, if the practice had the practical effect of disadvantaging competitors or steering referrals, this could be evidence that the practice was not directly related to the safeguarding the confidentiality, integrity, and availability of EHI. We propose that such an inference would also not be warranted where the actor has not met the other conditions of this exception proposed below, as where the actor's policies were not developed or implemented in a reasonable manner; its security policies or practices were not tailored to specific risks; or it applied its security policies or practices in an inconsistent or discriminatory manner.

The Practice Must Be Tailored to the Specific Security Risk Being Addressed

To qualify for this exception, we propose that an actor's security-related practice must be tailored to specific security risks that the practice actually addressed. This condition necessarily presupposes that an actor has carefully evaluated the risk posed by the security threat and developed a considered response that is tailored to mitigating the vulnerabilities of the actor's health IT or other related systems. For example, the awareness of a security vulnerability in a particular HIE's technology may justify a health care provider's suspending access to EHI from that organization or by participants of that HIE, but only for the period in which the threat persists. In contrast, a response that suspended access by all HIEs or that persisted even after the HIE had addressed the security vulnerability in its technology would not be tailored to address specific risks and would not meet this condition.

As another example, it may be reasonable for a health care provider to refuse to grant access to EHI when an individual has been unable to prove her identity. However, the actor's identity proofing practice would have to be tailored to address risks specifically associated with the disclosure of EHI to unauthorized individuals. For example, identity proofing requirements might be tailored if the practice is based on a risk assessment and best practice policies and procedures and is applied consistently and in a non-discriminatory manner. However, we believe an identity proofing requirement would not be tailored if it were not based on an objectively reasonable security risk assessment and a careful consideration of alternative approaches that could adequately address the specific risk of patient misidentification in a less restrictive fashion.

As a final example, an actor's decision to deny access to the EHI it maintains may be reasonable if the practice responds to a request for EHI from a patient-facing website or application that causes the actor's system to raise a malicious software detection alert or if the request comes from a website or application listed on a security ''blacklist.'' However, we propose that the actor's response must be tailored to the specific threat. Among other things, the denial of access must be limited to the patient and/or their personal software. So as to ensure that the response is properly tailored, it would be best practice for actors to ensure that they communicate to those persons whose access was denied the reason for the denial of access, and communicate objective timeframes (if feasible to do so) and other parameters for when access would be granted or restored. Moreover, we propose that, to the extent that the practice implements an organizational security policy, the policy must align with applicable consensus-based standards or best practices for responding to these types of incidents. Disagreement with the individual about the worthiness of the third party as a recipient of EHI, or even concerns about what the third party might do with the EHI, except for reasons such as those listed in the ''preventing harm'' exception, are not acceptable reasons to deny an individual's request.

Practice Must Be Implemented in a Consistent and Non-Discriminatory Manner

We propose that in order for a practice to qualify for this proposed exception, the actor's practice must have been implemented in a consistent and non-discriminatory manner. This condition would provide basic assurance that the purported security practice is directly related to a specific security risk and is not being used to interfere with access, exchange, or use of EHI for other purposes to which this exception does not apply.

As an illustration solely of the non-discriminatory manner condition, consider a health IT developer of certified health IT that offers apps to its customers via an app marketplace. If the

[121] 45 CFR 164.306(d)(3)(ii)(B)(1); 45 CFR 164.316(b)(1).

developer requires that third-party apps sold (or made available) via the developer's app marketplace meet certain security requirements, those security requirements must be imposed in a non-discriminatory manner. This would mean, for example, that if a developer imposed a requirement that third-party apps include two-factor authentication for patient access, the developer would need to ensure that the same requirement was imposed on, and met by, all other apps, including any apps made available by the developer itself. To note, such a developer requirement must also meet the other conditions of this exception (*e.g.,* the condition that the practice be tailored to the specific security risk being addressed).

Practices That Implement an Organizational Security Policy

As discussed above, an actor's approach to information security management will reflect the actor's particular size, organizational structure, and risk posture. Because of this, it is important that actors develop and implement organizational policies that secure EHI. We propose that, where an actor has documented security policies that align with applicable consensus-based standards, and where the policies are implemented in a consistent and non-discriminatory manner, a practice's conformity with such policies would provide a degree of assurance that the practice was reasonable and necessary to address specific security risks and thus should not constitute information blocking. Conversely, a practice that went beyond an actor's established policies or practices by imposing security controls that were not documented, would not qualify for this exception under this condition (although the actor may be able to qualify under the alternative basis for practices that do not implement a security policy). Further, such practices would be suspect under the information blocking provision if there were indications that the actor's security-related justifications were a pretext or after-the-fact rationalizations for its actions or was otherwise unreasonable under the circumstances.

We reiterate that, to the extent that an actor seeks to justify a practice on the basis of its organizational security policies, such policies must be in writing and implemented in a consistent and non-discriminatory manner. As noted above, what a policy requires will depend on the facts and circumstances. However, we propose that to support a presumption that a practice conducted pursuant to the actor's security policy was reasonable, the policy would have to meet the following conditions.

- *Risks identified and assessed.* The actor's security policy must be informed by an assessment of the security risks facing the actor. While we do not propose any requirements as to a risk assessment, we note that a good risk assessment would use an approach consistent with industry standards,[122] and would incorporate elements such as threat and vulnerability analysis, data collection, security measures, likelihood of occurrence, impact, level of risk, and final reporting.[123]
- *Consensus-based standards or best practice guidance.* The actor's policy must align with one or more applicable consensus-based standards or best practice guidance. At present, examples of relevant best practices for development of security policies include, but are not limited to: NIST–800–53 Rev. 5; the NIST Cybersecurity Framework; and NIST SP 800–100, SP 800–37 Rev. 2, SP 800–39, as updated and as interpreted through formal guidance. Best practice guidance on security policies is also developed by consensus standards bodies such as ISO, IETF, or IEC. HIPAA covered entities and business associates may be able to leverage their HIPAA Security Rule compliance activities and can, if they choose, align their security policy with those parts of the NIST Cybersecurity Framework that are referenced in the HIPAA Security Rule Crosswalk to NIST Cybersecurity Framework to satisfy this condition. Relevant consensus-based standards and frameworks provide actors of varying size and resources with the flexibility needed to apply the right security controls to the right information systems at the right time to adequately address risk.
- *Objective timeframes and other parameters.* We propose that the actor's security policy must provide objective timeframes and common terminology used for identifying, responding to, and addressing security incidents. Examples of acceptable sources for development of a security response plan include: NIST Incident Response Procedure (*https://csrc.nist.gov/publications/detail/sp/800-61/rev-2/final*), US–CERT for interactions with government systems (*https://www.us-cert.gov/government-users/reporting-requirements*), and ISC–CERT for critical infrastructure (*https://ics-cert.us-cert.gov/*).

As a point of clarification, we note that an actor's compliance with the HIPAA Security Rule (if applicable to the actor) would be relevant to, but not dispositive of, whether the actor's policies and procedures were objectively reasonable for the purpose of this exception. An actor's documentation of its security policies and procedures for compliance with the Security Rule may not offer a basis to evaluate whether the actor's security practices unnecessarily interfere with access, use, or exchange of EHI. For example, it could be difficult to determine whether a practice unnecessary interferes with exchange of EHI based on a review of the customized PHI data flow diagram the actor prepared as part of its Security Rule risk analysis. We believe that a documented policy that provides explicit references to consensus-based standards and best practice guidance (such as the NIST Cybersecurity Framework) offer an objective and robust means for ONC and the OIG to evaluate the reasonableness of a particular security control for the purpose of this exception.

We recognize that, as a practical matter, some actors (such as small health care providers or those with limited resources) may have organizational security policies that are less robust or that otherwise fall short of the minimum conditions proposed above. As discussed immediately below, we propose that in these circumstances an actor could still benefit from this proposed exception by demonstrating that the practice at issue was objectively reasonable under the circumstances, without regard to a formal policy.

Practices That Do Not Implement an Organizational Security Policy

While we expect that most security practices engaged in by an actor will implement an organizational policy, we recognize that EHI security may present novel and unexpected threats that even a best-practice risk assessment and security policy cannot anticipate. If a practice that does not implement an organizational policy is to qualify for this exception, however, it must meet certain conditions. The actor's practice must, based on the particularized facts and circumstances, be necessary to mitigate the security risk. Importantly, we propose that the actor would have to demonstrate that it considered reasonable and appropriate alternatives that could have reduced the likelihood of interference with access, exchange, or use of EHI, and that there were no reasonable and appropriate alternatives

[122] See OCR, Guidance on Risk Analysis, *https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html?language=es.*

[123] ONC and OCR have jointly launched the HHS HIPAA Security Risk Assessment (SRA) Tool, *https://www.healthit.gov/providers-professionals/security-risk-assessment-tool.*

that were less likely to interfere with access, exchange or use of EHI.

We note that an actor's consideration of reasonable and appropriate alternatives will depend on the urgency and nature of the security threat in question. We anticipate that an actor's qualification for this exception would accommodate exigent circumstances. For example, we would not expect an actor to delay the implementation of a security measure in response to an emergency on the basis that it has not yet been able to initiate a fully realized risk assessment process. However, we expect that in these exigent circumstances, where the actor has implemented a security practice without first considering whether there were reasonable and appropriate alternatives that were less likely to interfere with access, exchange or use of EHI, the actor would expeditiously make any necessary changes to the practice based on the actor's consideration of reasonable and appropriate alternatives that are less likely to interfere with access, exchange or use of EHI. We propose that the exception would apply in these instances so long as an actor takes these steps and complies with all other applicable conditions.

We encourage comment on these conditions and our overall approach to this proposed exception, including whether our proposal provides adequate flexibility for actors to implement measures that are commensurate to the threats they face, the technology infrastructure they possess, and their overall security profiles and, equally important, whether this exception adequately mitigates the risk that actors will adopt security policies that are unnecessarily restrictive or engage in practices that unreasonably interfere with access, exchange, or use of EHI. Commenters are encouraged to propose additional conditions that may be necessary to ensure that the exception is tailored and does not extend protection to practices that are not reasonable and necessary to promote the security of EHI and that could present information blocking concerns. We also seek comment on whether the use of consensus-based standards and guidance provides an appropriate reference point for the development of security policies. Finally, commenters may wish to offer an alternative basis for identifying practices that do not offer a security benefit (compared with available alternatives) but that cause an information blocking harm by interfering with access, exchange, or use of EHI.

4. Recovering Costs Reasonably Incurred

We propose to establish an exception to the information blocking provision that would permit the recovery of certain costs reasonably incurred to provide access, exchange, or use of EHI. The exception and corresponding conditions are set forth in the proposed regulation text in § 171.204. We interpret the definition of information blocking to include *any* fee that is likely to interfere with the access, exchange, or use of EHI (see discussion in section VIII.C.4.c.iv). We anticipate that this interpretation may be broader than necessary to address genuine information blocking concerns and could have unintended consequences on innovation and competition. Specifically, unless we establish an exception, actors may be unable to recover costs that they reasonably incur to develop technologies and provide services that enhance interoperability. This could undermine the ultimate goals of the information blocking provision by diminishing incentives to invest in, develop, and disseminate interoperable technologies and services that enable more robust access, exchange, and use of EHI. Therefore, we propose to establish an exception that would permit the recovery of certain costs that we believe are unlikely to present information blocking concerns and would generally promote innovation, competition, and consumer welfare, provided certain conditions are met. We note that complying with the requirements of this exception would not prevent an actor from making a profit in connection with the provision of access, exchange, or use of EHI. Indeed, the costs recoverable under this proposed exception could include a reasonable profit, provided that all applicable conditions were met.

The exception would be subject to strict conditions to prevent its potential misuse. Specifically, we are concerned that a broad or insufficiently tailored exception for the recovery of costs could protect rent-seeking, opportunistic fees, and exclusionary practices that interfere with the access, exchange, and use of EHI. These practices fall within the definition of information blocking and reflect some of the most serious concerns that motivated its enactment (*see* section VIII.B of this preamble). For example, in the Information Blocking Congressional Report, we cited evidence of wide variation in fees charged for health IT products and services. While we cautioned that the issue of fees is nuanced, and that variations in fees could be attributable in part to different technology architectures, service models, capabilities, service levels, and other factors, we concluded that these factors alone could not adequately explain all of the variation in prices that we had observed. Based on these and other indications, we concluded that some actors were engaging in opportunistic pricing practices or, in some cases, charging prices designed to deter connectivity or exchange with competing technologies or services.

In the time since we published the Information Blocking Congressional Report, these practices have persisted and, in certain respects, become more pronounced. In a national survey of HIE executives published in 2017, 47% of respondents reported that EHR developers ''often/routinely'' charge high fees for exchange that are unrelated to cost, and another 40% reported that they ''sometimes'' do.[124] Meanwhile, we have continued to receive credible evidence of rent-seeking and other opportunistic behaviors, such as fees for data export and data portability that are not plausibly related to any reasonable time, materials, or other costs that a developer would reasonably incur to provide these services. And, while some practices described in the Information Blocking Congressional Report have become less prevalent (such as the charging of per-transaction fees), other practices have emerged that are equally concerning.

As just one illustration, some EHR developers have begun conditioning access or use of customer EHI on revenue-sharing or royalty agreements that bear no plausible relation to the costs incurred by the EHR developer to grant access to the EHI. We have also heard of discriminatory pricing policies that have the obvious purpose and effect of excluding competitors from the use of interoperability elements. Many of the industry stakeholders who shared their perspectives with us in listening sessions prior to this proposed rule, including several health IT developers of certified health IT, condemned these practices and urged us to swiftly address them.

In light of these concerns, we propose that this exception would apply only to the recovery of certain costs and only when the actor's methods for recovering such costs comply with certain conditions at all relevant times. As discussed in more detail below, these conditions would require that the costs the actor recovered were reasonably

[124] Julia Adler-Milstein and Eric Pfeifer, *Information Blocking: Is It Occurring And What Policy Strategies Can Address It?*, 95 Milbank Quarterly 117, 124–25 (Mar. 2017), *available at http://onlinelibrary.wiley.com/doi/10.1111/1468-0009.12247/full.*

incurred and did not reflect costs that are speculative or subjective. Actors would also be required to allocate costs in an appropriate manner and to use objective and permissible criteria when charging fees to recover those costs. Further, the exception would not apply to certain fees, such as those based on the profit or revenue associated with the use of EHI (either being earned by the actor, or that could be realized by another individual or entity) that exceed the actor's reasonable costs for providing access, exchange, or use of the EHI. We specify certain prohibited fees below.

Finally, the exception would provide additional conditions applicable to fees charged in connection with: (1) The certified APIs described in § 170.404; and (2) the EHI export capability proposed in § 170.315(b)(10) for the purposes of switching health IT or to provide patients their electronic health information. We emphasize that access to EHI that is provisioned by supplying some form of physical media, such as paper copies (where the EHI is printed out), or where EHI is copied onto a CD or flash-drive, would not be a practice that implicated the information blocking provision provided that the fee(s) charged for that access complied with HIPAA (45 CFR 164.524(c)(4)).

Our intention with this exception is not to set any particular cost that would be considered ''reasonably incurred,'' but rather to allow the market to define the appropriate price so long as certain methods are followed and certain criteria are met.

Requirement That Costs Be Reasonably Incurred

Regardless of the type of cost at issue, a basic condition of this proposed exception is that any costs the actor seeks to recover must have been reasonably incurred to provide the relevant interoperability elements to enable access, exchange, or use of EHI. Ultimately, whether a cost was reasonably incurred will depend on the particular facts and circumstances. We believe this fact-based approach is appropriate in light of the considerable diversity in the types of costs that actors might incur and the range of factors that could bear on the reasonableness of those costs. For example, the costs of developing software may vary with the purposes it is intended to serve, the settings in which it will be deployed, the types and scope of capabilities included, and the extent to which these development efforts build on existing development efforts and know-how. Additionally, the costs of providing services, including the implementation of technology in production environments, may vary based on the technology design or architecture, individual customer needs, local implementation conditions, and other factors. An analysis of costs would also account for different distribution and service models under which the costs are calculated. We seek comment on these and other considerations that may be relevant to assessing the reasonableness of costs incurred for purposes of this exception.

Method for Recovering Costs

To qualify for the exception, we propose that the method by which the actor seeks to recover its costs must be reasonable and non-discriminatory. This would require that the actor base its recovery of costs on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests. We emphasize that this proposal does not mean that the actor must apply the same prices or price terms for all persons or classes of persons to whom it provides the services. However, any differences in prices or price terms would have to be based on actual differences in the costs that the actor incurred or other reasonable and non-discriminatory criteria. We further propose to require that the method by which the actor recovers its costs must be reasonably related to the actor's costs of providing the type of access, exchange, or use to, or at the request of, the person or entity to whom the fee is charged.

We also propose that the method by which the actor recovers its costs must be reasonably allocated among all customers to whom the technology or service is supplied, or for whom the technology is supported. A reasonable allocation of costs would require that the actor allocate its costs in accordance with criteria that are reasonable and between only those customers that either cause the costs to be incurred or benefit from the associated supply or support of the technology. If an actor developed technology that could be supplied to multiple customers with minimal tailoring, the core costs of developing its technology should be allocated between those customers when recovered as a fee. The actor would not be permitted to recover the total of its core costs from each customer. Similarly, when an actor uses shared facilities and resources to support the usage of technology, it would need to ensure that those shared costs were reasonably allocated between all of the customers that benefited from them. However, whenever an actor is required to provide services and incur costs that are unique to a particular customer, it would not need to distribute those costs among other customers that had deployed technology.

In addition, the exception would not apply if the method by which the actor recovers its costs is based, in any part, on whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor. The use of such criteria would be suspect because it suggests the fee the actor is charging is not based on its reasonable costs to provide the services and may have the purpose or effect of excluding or creating impediments for competitors, business rivals, or other persons engaged in developing or enabling the use of interoperable technologies and services.

Last, we propose that the method by which the actor recovers its costs must not be based on the sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access to, exchange of, or use of electronic health information, including the secondary use of such information, that *exceeds* the actor's reasonable costs for providing access, exchange, or use of electronic health information. We emphasize that such revenue-sharing or profit-sharing arrangements would *only* be acceptable and covered by the exception if such arrangements are designed to provide an alternative way to recover the costs reasonably incurred for providing services.

We seek comment on these conditions and other issues we should consider in assessing whether the methodology by which an actor distributes costs and charges fees should be considered reasonable and necessary for purposes of this exception. In particular we are considering whether to introduce specific factors and methods for assessing when profit will be reasonable. For example, should the pro-competitive or efficiency-adding aspect of an actor's approach to providing access, exchange, or use of EHI be taken into account when assessing the reasonableness of the profit recovered by an actor? We also ask commenters to consider whether there are specific use cases for which actors' profits should be limited or prohibited. We request that commenters provide as much detail as possible when describing methods for quantifying profits and evaluating their reasonableness.

Costs Specifically Excluded

We propose that certain costs should be explicitly excluded from this exception regardless of the method for recovering the costs. We have proposed these excluded costs, which are detailed below, in an effort to provide additional clarity about the scope of this exception and to create guardrails for preventing potential misuse of the exception.

Costs Due to Non-Standard Design or Implementation Choices

We propose that this exception would not permit the recovery of any cost that the actor incurred due to the health IT being designed or implemented in non-standard ways that unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using EHI. To the extent that such costs can be reasonably avoided, we believe that actors should internalize the costs of such behaviors, which do not benefit consumers, and which create unnecessary impediments to access, exchange, and use of EHI. As an illustration, if a health IT developer of certified health IT designed its database tables or other aspects of its technology in ways that make exporting or converting EHI to other formats difficult, the developer could not claim that its costs to provide data conversion services to customers are reasonably incurred. Such costs would not be eligible under this exception (and might implicate the information blocking provision for the reasons noted in section VIII.C.4.c.v of this preamble).

We welcome comments on the exclusion of these types of costs.

Subjective or Speculative Costs

We propose to limit this exception to the recovery of costs that an actor *actually* incurred to provide the relevant interoperability element or group of elements (which may comprise either products or services). We propose that this exception would not permit the recovery of certain types of costs that are subjective or speculative. We note two important examples of this limitation.

First, an actor would not be permitted to recover any costs associated with intangible assets (including depreciation or loss of value), other than the actual development or acquisition costs of such assets. For example, an actor could not charge a customer a fee based on the purported ''cost'' of allowing the customer to use the actor's patented technology, computer software, databases, trade secrets, copyrighted works, and the like. We understand that the customer's use of the asset could be considered a ''cost'' in the sense that, were it not for the information blocking provision, the actor could charge a royalty or other fee for the use of its intangible assets. For this reason, in section VIII.D.6, we propose to permit an actor to license most interoperability elements on reasonable and non-discriminatory terms, subject to certain conditions. For purposes of this more general exception, however, we believe it would be inappropriate to permit an actor to charge a fee based on these considerations, which are inherently subjective and could invite the kinds of rent-seeking and opportunistic pricing practices that fall squarely within the definition of information blocking. We clarify that an actor's practices could qualify for both this exception (recovering costs reasonably incurred) and the exception for licensing of interoperability elements on reasonable and non-discriminatory terms in section VIII.D.6. In that case, the actor could recover costs under both exceptions.

Second, and for similar reasons, an actor would not be permitted to recover costs that are speculative. The exception would not apply to ''opportunity costs,'' such as the revenues that an actor could have earned had it not provided the interoperability elements. We clarify that the exclusion of opportunity costs would not preclude an actor from recovering its reasonable forward-looking cost of capital. We believe these costs are relatively concrete and that permitting their recovery will protect incentives for actors to invest in developing and providing interoperability elements.

Fee Prohibited by 45 CFR 164.524(c)(4)

We also propose that the exception would not apply to fees prohibited by 45 CFR 164.524(c)(4). The HIPAA Privacy Rule permits a covered entity to impose a reasonable, cost-based fee if the individual requests a copy of the PHI (or agrees to receive a summary or explanation of the information). The fee may include only the cost of: (1) Labor for copying the PHI requested by the individual, whether in paper or electronic form; (2) supplies for creating the paper copy or electronic media (*e.g.,* CD or USB drive) if the individual requests that the electronic copy be provided on portable media; (3) postage, when the individual requests that the copy, or the summary or explanation, be mailed; and (4) preparation of an explanation or summary of the PHI, if agreed to by the individual (45 CFR 164.524(c)(4)). The fee may not include costs associated with verification; documentation; searching for and retrieving the PHI; maintaining systems; recouping capital for data access, storage, or infrastructure; or other costs not listed above even if such costs are authorized by state law.

Individual Electronic Access

We propose that this exception would not apply if the actor charged a fee based in any part on the electronic access by an individual or their personal representative, agent, or designee to the individual's EHI. Such fees are distinguished from the cost-based fees that a covered entity is permitted to charge individuals for the provision of copies of ePHI under HIPAA (45 CFR 164.524(c)(4)), and similar allowable costs under state privacy laws, which would *not* be excluded from the costs recoverable under this exception. To be clear, access to EHI that is provisioned by supplying some form of physical media, such as paper copies (where the EHI is printed out), or where EHI is copied onto a CD or flash-drive, would not be a practice that implicated the information blocking provision provided that the fee(s) charged for that access complied with HIPAA (45 CFR 164.524(c)(4)).

A fee based on electronic access by an individual or their personal representative, agent, or designee to the individual's EHI, in contrast, would arise if an actor sought to impose on individuals, or their personal representatives, agents, or designees, a fee that operated as a toll for the provision of electronic access. For example, a health care provider that charges individuals a fee in order that the individuals be given access to their EHI via the health care provider's patient portal or another mode of web-based delivery, would not be able to benefit from this exception. Similarly, where an individual authorizes a consumer-facing app to retrieve EHI on the individual's behalf, it would be impermissible for an actor to charge the app or its developer a fee to access or use APIs that enable access to the individual's EHI. This would be true whether the actor is a supplier of the API technology or an individual or entity that has deployed the API technology, such as a health care provider.

Export and Portability of EHI Maintained in EHR Systems

The definition of information blocking specifically mentions transitions between health IT systems and the export of complete information sets as protected forms of access, exchange, and use (*see* section 3022(a)(2)(C)(i) of the PHSA). In our experience, health care providers

frequently encounter rent-seeking and opportunistic pricing practices in these and other contexts in which they are attempting to export EHI from their systems for use in connection with other technologies or services that compete with or could reduce the revenue opportunities associated with an EHR developer's own suite of products and services. As discussed in section VIII.C.5.b.iii of this preamble, most EHI is currently maintained in EHRs and other source systems that use proprietary data models or formats; this puts EHR developers in a unique position to block the export and portability of EHI for use in competing systems or applications, or to charge rents for access to the basic technical information needed to facilitate the conversion or migration of data for these purposes. The concerns are compounded by the fact that EHR developers rarely disclose in advance the fees they will charge for data export and data portability services (*see* 80 FR 62719; 80 FR 16880–81).

For the reasons above, we propose that fees charged for the export, conversion, or migration of data from an EHR technology would not qualify for the exception unless they also meet two additional conditions.

First, we propose that health IT developers of certified health IT would, for purposes of this exception, be precluded from charging a fee to perform an export of EHI via the capability of health IT certified to the proposed 2015 Edition ''EHI export'' certification criterion (§ 170.315(b)(10)) for the purposes of switching health IT systems or to provide patients their EHI. As part of the ''Assurances'' Condition of Certification, health IT developers that produce and electronically manage EHI would need to be certified to the ''EHI export'' criterion and provider the functionality to its customers (*see* § 170.402(a)(4) and section VII.B.2.b of this preamble). As described in section IV.C.1 of this preamble, the ''EHI export'' certification criterion is intended to provide a baseline capability to export EHI from certified health IT in a commercially reasonable format in support of transitioning of EHI between health IT systems and patient access. Fees or limitations associated with the use of this capability (as distinguished from deployment or other costs reasonably incurred by the developer) would not receive protection under the exception and may be suspect under the information blocking provision. We clarify that this condition would not preclude a developer from charging a fee to deploy the EHI export capability in a health care provider's production environment, or to provide additional services in connection with this capability other than those reasonably necessary to enable its intended use. For example, this condition would not preclude a developer from charging a fee to perform an export of EHI via the capability of health IT certified to the proposed § 170.315(b)(10) for a third-party analytics company. We emphasize once again that these excluded fees are distinguished from the cost-based fees that a covered entity is permitted to charge individuals for the provision of copies of ePHI under HIPAA (45 CFR 164.524(c)(4)), and similar allowable costs under state privacy laws, which would *not* be excluded from the costs recoverable under this exception.

We note that, because this certification criterion provides only a baseline capability for exporting data, we anticipate that health IT developers of certified health IT will need to provide other data portability services to facilitate the smooth transition of health care providers between different health IT systems. We propose that such fees may qualify for protection under the exception, but only if they meet the other conditions described above and in proposed § 171.205(a).

Second, we propose that the exception would not apply to a fee to export or convert data from an EHR technology unless such fee was agreed to in writing at the time the technology was acquired, meaning when the EHR developer and the customer entered into a contract or license agreement for the EHR technology. This condition is designed to promote the disclosure of fees upfront and thereby reduce the potential for actors to engage in installed-base opportunism or attempting to use fees to discourage data portability.

Compliance With the Condition of Certification Specific to API Technology Suppliers and API Data Providers

We note that health IT developers of certified health IT subject to the API Condition of Certification proposed in § 170.404 may not charge certain types of fees and are subject to more specific cost accountability provisions than apply generally under this proposed exception. We believe that the failure of developers to comply with these additional requirements would impose impediments to consumer and other stakeholder access to EHI without special effort and would be suspect under the information blocking provision. We propose, therefore, that a health IT developer of certified health IT subject to the API Condition of Certification must comply with all requirements of that condition for all practices and at all relevant times in order to qualify for this exception.

We also believe that a health care provider that acts as an API Data Provider, should be subject to the same constraints. For example, the API Condition of Certification prohibits a health IT developer from charging a usage fee to patient-oriented apps. We believe information blocking concerns would arise if a provider were to charge such a fee, notwithstanding the fact that the provider is not subject to the certification requirements. For this reason, we propose that, if the actor is an API Data Provider, the actor is only permitted to charge the same fees that an API Technology Supplier is permitted to charge to recover costs consistent with the permitted fees specified in the Condition of Certification in § 170.404. In other words, to the extent that a provider is an API Data Provider, the provider will not qualify for this exception if it charges any fee that a health IT developer of certified health IT would be prohibited from charging under the API Condition of Certification.

Application of the Exception to Individual Practices

We clarify that the conditions of this exception, including those governing the methodology and criteria by which an actor calculates and distributes its costs, must be satisfied for *each and every* fee that an actor charges to a customer, requestor, or other person. For example, if an actor uses a cost allocation methodology that does not meet the requirements of the exception, each fee charged on the basis of that methodology would be a suspect practice under the information blocking provision. All applicable conditions of the exception must be met at all relevant times for each practice.

We request comment on this proposed exception. Specifically, we ask commenters to consider alternate approaches to the exception that would also achieve the goal of allowing actors to recover certain types of costs that would promote innovation, competition and consumer welfare and that are unlikely to present information blocking concerns. In assessing other potential approaches to this exception, we encourage commenters to contemplate such considerations as enforceability, potential burden on the parties, and overall effectiveness in meeting the above stated goals.

5. Responding To Requests That are Infeasible

We propose to establish an exception to the information blocking provision that would permit an actor to decline to provide access, exchange, or use of EHI in a manner that is infeasible, provided certain conditions are met. The exception and corresponding conditions are set forth in the proposed regulation text in § 171.205. We propose that this exception would not apply when a response is required by law. As discussed in section VIII.C.5 of this preamble, we propose that the information blocking provision would be implicated if an actor were to refuse to facilitate access, exchange, or use of EHI, either as a general practice or in isolated instances. However, we believe that in certain circumstances legitimate practical challenges beyond an actor's control may limit its ability to comply with requests for access, exchange, or use. In some cases, the actor may not have—and may be unable to obtain—the requisite technological capabilities, legal rights, financial resources, or other means necessary to provide a particular form of access, exchange, or use. In other cases, the actor may be able to comply with the request, but only by incurring costs or other burdens that are clearly unreasonable under the circumstances.

Actors confronted with these types of practical challenges may be concerned about their exposure under the information blocking provision, which could lead to inefficient outcomes. For example, health care providers may feel compelled to entertain requests to enable or support means of exchange or use that would be disruptive to health care operations or that are not financially sustainable. In some of these instances, the actor may be able, but reluctant, to offer alternative means that would meet the requestor's needs while reducing the burden on the actor, leading to more efficient outcomes overall. Actors could also be forced into a ''reactive'' posture that limits their ability to make holistic decisions and to implement health IT in a considered, scalable way that facilitates robust interoperability and information sharing. These outcomes would be counterproductive to the policies the information blocking provision encompasses.

The proposed exception would alleviate some of these concerns while safeguarding against pretextual and other unreasonable refusals to provide access, exchange, or use of EHI. The exception would permit an actor to decline a request in certain narrowly-defined circumstances when doing so would be infeasible (or impossible) and when the actor otherwise did all that it reasonably could do under the circumstances to facilitate alternative means of accessing, exchanging, and using the EHI. We believe this approach is principled and tailored in a manner that will promote basic fairness and encourage parties to work cooperatively to implement efficient solutions to interoperability challenges. Importantly, to ensure that the exception is not used inappropriately, we propose a structured, fact-based approach for determining whether a request was in fact ''infeasible'' within the meaning of this exception. This approach would be limited to a consideration of factors specifically delineated in the exception and that focus the infeasibility inquiry on the immediate and direct financial and operational challenges of facilitating access, exchange, and use, as distinguished from more remote, indirect, or speculative types of injuries.

We encourage comment on these and other aspects of this proposal, which are described in more detail below.

i. Infeasibility of Request

To qualify for this proposed exception, in addition to meeting other conditions, we propose that compliance with the request for access, exchange, or use must be infeasible. We propose a two-step test that an actor would need to meet in order to demonstrate that a request was infeasible.

Complying With the Request Would Impose a Substantial Burden on the Actor

Under the first step of the infeasibility test, the actor would need to show that complying with the particular request in the manner requested would impose a substantial burden on the actor that is unreasonable under the circumstances. We anticipate that in most cases an actor would meet this requirement by showing that it did not have, and could not readily obtain, the requisite technological capabilities, legal rights, or other means necessary to facilitate the particular type of access, exchange, or use requested. Additionally, the requirement could be met by showing that, had it complied with the request, the actor would have experienced a significant disruption to its health care or business activities or would have incurred significant unbudgeted costs. We would also consider other analogous outcomes that impact the actor's health care or business activities in a direct and substantial way. We seek comment on what those outcomes might be and encourage commenters to be as detailed and specific as possible.

In determining whether these or other types of burdens are substantial, we would consider the actor's particular circumstances, including the type of actor; the nature and purpose of its business or other activities; and the financial, technical, and other resources and expertise at its disposal. In addition, we would also consider any offsetting benefits to the actor of providing the requested access, exchange, or use, such as facilitating the actor's compliance with statutory and regulatory requirements. Due to the variability of circumstances, ONC would take a fact-specific approach to these analyses.

As an illustration, a small physician practice with limited financial and technical resources may find it burdensome to accommodate requests from other providers to establish and maintain outbound interfaces from the practice's EHR system that it neither needs for its own health care activities nor to comply with any regulatory requirements. In contrast, a large health system with a well-resourced IT department may be in a position to accommodate such requests without significant disruption to its business and at relatively minimal additional expense relative to its overall IT budget. Similarly, custom development or other activities that might be burdensome for a health care provider with limited technical expertise may not result in a substantial burden for a health IT developer, exchange, or network whose business is to develop and provide technological solutions.

We clarify that the exception focuses solely on the immediate and direct financial and operational challenges of facilitating access, exchange, or use. The exception does not apply—and we would give no weight—to any putative burdens that an actor experiences that relate primarily to the actor's pursuit of an economic advantage, such as its ability to charge higher prices, capture additional revenue streams, maintain or increase its market share, or otherwise pursue its own economic interests. To the extent that these interests merit an exception under the information blocking provision, they are addressed under the exceptions proposed in §§ 171.204 and 171.206. In the same way, the exception would not apply to any putative burdens that are more appropriately examined under another proposed exception. For example, an actor could not claim that it is burdensome to implement a tailored organizational patient safety policy under proposed § 171.201(b) or to

develop and implement policies and procedures for satisfying preconditions imposed by state or federal privacy laws for the provision of access, exchange, or use of EHI under proposed § 171.202(b).

The Burden Imposed on the Actor Would Be Plainly Unreasonable Under the Circumstances

To show that a request for access, exchange, or use was infeasible, the actor must not only demonstrate that complying with the request would have resulted in a substantial burden, as described above; the actor must also demonstrate that requiring it to comply with the request—and thus to assume the substantial burden demonstrated under the first part of the test—would have been plainly unreasonable under the circumstances. Whether it would have been plainly unreasonable for the actor to assume the burden of providing access, exchange, or use will be highly dependent on the particular facts and circumstances. While for this reason we do not believe that bright-line rules would be appropriate, we do propose to rely primarily on the following key factors enumerated in proposed § 171.205(a)(1):

- The type of EHI and the purposes for which it may be needed;
- The cost to the actor of complying with the request in the manner requested;
- The financial, technical, and other resources available to the actor;
- Whether the actor provides comparable access, exchange, or use to itself or to its customers, suppliers, partners, and other persons with whom it has a business relationship;
- Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which EHI is accessed or exchanged;
- Whether the actor maintains ePHI on behalf of a covered entity, as defined in 45 CFR 160.103, or maintains EHI on behalf of the requestor or another person whose access, exchange, or use of EHI will be enabled or facilitated by the actor's compliance with the request;
- Whether the requestor and other relevant persons can reasonably access, exchange, or use the information from other sources or through other means; and
- The additional cost and burden to the requestor and other relevant persons of relying on alternative means of access, exchange, or use.

As these factors suggest, the starting point for our inquiry would be to identify the type of EHI at issue and the purposes for which it may be needed. As explained in section VIII.C.5.b.i. of this preamble, certain types of EHI—namely, observational health information—give rise to a heightened risk of interference under the information blocking provision. For purposes of this exception and the information blocking provision more generally, the actor has a strong duty to facilitate the availability and use of this information, which may be needed for important activities for which timely and complete access to EHI is essential, such as providing patients with their EHI; enabling the use of EHI for treatment and care coordination; and making EHI available for quality improvement and population health management activities.

Next, we would consider the severity of the burdens that the actor would have experienced to provide the access, exchange, or use of EHI in the manner requested. For this purpose, we would consider both the burden on the actor of complying with the specific request at issue as well as the burden the actor would experience if it was required to comply with similar types of requests. We would also consider the observed or likely frequency of such requests. As already discussed, we anticipate that the extent of any burden would depend in part on the particular circumstances of the actor. In addition, in considering the burden to the actor, we would also consider any offsetting benefits to the actor of providing the requested access, exchange, or use.

Having ascertained the nature and severity of any burdens that the actor would assume to provide the requested access, exchange, or use, we would balance these burdens against the countervailing costs to the requestor and other persons (including consumers) who would be harmed by the actor's refusal to provide the requested access, exchange, or use. Importantly, we would consider whether the requestor and other persons could have obtained the EHI from other sources or through other means, including those made available by the actor as an accommodation to the requestor, as discussed in more detail below. If alternative means were available, we would examine the extent to which they would have been appropriate for the purposes for which the EHI or interoperability elements were needed and the extent to which requiring the requestor to pursue these alternative means would impose additional costs or burdens on the requestor and other persons. For example, if the EHI was readily available through other means that were equally efficacious, the actor's refusal to provide yet one more means of access, exchange, or use might impose only a minimal burden on the requestor and other persons' use of the EHI. In contrast, if the actor conditions critical technology or infrastructure for accessing, exchanging, or using EHI, or if its control over other interoperability elements means that EHI cannot be efficiently accessed, exchanged, or used without the actor's cooperation, requiring the requestor to pursue other means of access, exchange, or use would likely be unrealistic and represent an insurmountable burden.

One final consideration would inform our analysis. We would consider the balancing of relative burdens in conjunction with the actor's control over interoperability elements. As an example, a dominant health IT developer of certified health IT or network that refuses to facilitate a particular form of access, exchange, or use with other entities would have to demonstrate an extreme burden relative to the need for access, exchange, or use in order to qualify for this exception. This exacting standard would also apply in other circumstances of dependence or reliance on the actor to facilitate access, exchange, or use. For example, a dominant health system that provides local health IT infrastructure would have to demonstrate an extreme hardship to justify denying interconnection requests or access to interoperability elements. Likewise, where the actor is a business associate of a covered entity, or owes some other special duty to the requestor, the actor could not qualify for this exception unless the cost or burden it would have borne was so extreme in comparison to the marginal benefits to the requestor that the request was clearly unreasonable by any objective measure.

We acknowledge that there may be situations when complying with a request for access, exchange, or use would be considered infeasible because an actor is unable to provide such access, exchange, or use due to unforeseeable or unavoidable circumstances that are outside the actor's control. For example, an actor could seek coverage under this exception if it is unable to provide access, exchange, or use of EHI due to a natural disaster (such as a hurricane, tornado or earthquake) or war. These are just a couple examples of such circumstances and are by no means an exhaustive list.

We emphasize that, consistent with the requirements for demonstrating that activities and practices meet the conditions of an exception proposed in section VIII.C.6.c of this preamble, the actor would need to produce evidence and ultimately prove that complying

with the request for access, exchange, or use in the manner requested would have imposed a clearly unreasonable burden on the actor under the circumstances.

We note that there are certain circumstances that we propose would not constitute a burden to the actor for purposes of this exception and shall not be considered in determining whether complying with a request would have been infeasible. We propose that it would not be considered a burden if providing the requested access, exchange, or use in the manner requested would have (1) facilitated competition with the actor; or (2) prevented the actor from charging a fee. Throughout this proposed rule, we have highlighted that one of the goals of the information blocking section is to promote competition, and allowing the argument that a request is infeasible because it facilitates competition with the actor would be antithetical to this goal. Similarly, an argument that a request is infeasible because it prevents the actor from charging a fee would also be outside the scope of this exception because such a result would not constitute a substantial, unreasonable burden that this exception seeks to address.

We request comment on the structured, fact-based approach we have proposed for determining whether a request was in fact ''infeasible'' within the meaning of this exception. We encourage comment on, among other issues, whether the factors we have specifically delineated above properly focus the infeasibility inquiry; whether our approach to weighing these factors is appropriate; and whether there are additional burdens, distinct from the immediate and direct financial and operational challenges contemplated above, that are similarly concrete and should be considered under the fact-based rubric of this exception.

ii. Duty to Timely Respond and Provide Reasonable Cooperation

In addition to demonstrating that a particular request or class of requests was infeasible, we propose that an actor would have to show that it satisfied several additional conditions. Specifically, to qualify for this exception, the actor must have timely responded to all requests relating to access, exchange, and use of EHI, including but not limited to requests to establish connections and to provide interoperability elements. Further, for any request that the actor claims was infeasible, the actor must have provided the requestor with a detailed written explanation of the reasons why the actor could not accommodate the request. Finally, the actor must have worked with the requesting party in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the EHI, as applicable. The actor's failure to meet any of these conditions would disqualify the actor from the exception and could also be evidence that the actor knew that it was engaging in practices that contravened the information blocking provision.

We clarify that the duty to timely respond and provide reasonable cooperation would necessarily be assessed from the standpoint of what is objectively reasonable for an individual or entity in the actor's position. For example, we would not expect a small physician practice to provide the same level of engagement and technical assistance to third parties as a large hospital or health system with considerable health IT resources and expertise at its disposal. In some circumstances, it may even be difficult for a small practice to comply with any request for access, exchange, and use that is more complicated than a simple request for a patient's personal health information. If there are such requests—and there could be—then small practices may be both unable to comply with such requests and poorly situated to assist requesting parties with alternatives. We provide these examples to emphasize that we will look at the specific facts and circumstances of each case to determine what is objectively reasonable.

We believe that these conditions will minimize the risk that this exception could protect improper refusals to provide interoperability elements, including naked refusals to deal as well as other practices, such as improper delays in access or exchange that would present information blocking concerns. Additionally, the requirements for an actor to timely respond and document its justifications for declining a request in writing would prevent an actor from using post hoc rationalizations to justify these and other improper practices. Finally, we believe that establishing a clear duty under the exception for actors to deal on reasonable terms with parties seeking to access, exchange, or use EHI will encourage parties to cooperate to identify and implement efficient solutions to interoperability challenges, thereby avoiding disputes that could lead to information blocking.

We encourage comment on the additional conditions and related considerations described above. Specifically, we request comment regarding potential obstacles to satisfying these conditions and improvements we could make to the proposed process.

6. Licensing of Interoperability Elements on Reasonable and Non-Discriminatory Terms

We propose to establish an exception to the information blocking provision that would permit actors to license interoperability elements on reasonable and non-discriminatory (RAND) terms, provided that certain conditions are met. The exception and corresponding conditions are set forth in the proposed regulation text in § 171.206. As discussed in section VIII.C.5.a of this preamble, the information blocking provision would be implicated if an actor were to refuse to license or allow the disclosure of interoperability elements to persons who require those elements to develop and provide interoperable technologies or services—including those that might complement or compete with the actor's own technology or services. Moreover, the information blocking provision would be implicated if the actor licensed such interoperability elements subject to terms or conditions that have the purpose or effect of excluding or discouraging competitors, rivals, or other persons from engaging in these pro-competitive and interoperability-enhancing activities. Thus, this licensing requirement would apply in both vertical and horizontal relationships. For instance, it would apply when a developer in a vertical relationship to the actor—a network in this example—wants to use interoperability elements in order to access the EHI maintained in the actor's network. The requirement would also apply when a rival network in a horizontal relationship to the actor (network) wants to use interoperability elements so that its network can be compatible with the applications that have already been developed for use with the actor's network.

We note that some licensees do not require the interoperability elements to develop products or services that can be interoperable with the actor's health IT. For instance, there may be firms that simply want to license the actor's technology for use in developing their own interoperability elements. Their interest would be for access to the technology itself—not for the use of the technology to interoperate with either the actor or its customers. This may be the case, for example, if the relevant intellectual property included patents that were applicable to other information technology applications outside of health IT. In such cases, the actor's licensing of its patents in such a

context would *not* implicate the information blocking provision.

Below are examples of situations that *would implicate* the information blocking provision (these examples are not exhaustive):

- An actor refuses to negotiate a license after receiving a request from a developer.
- An actor offers a license at the request of a developer, but only at a royalty rate that exceeds a RAND rate.
- An actor offers a license to a competitor at a royalty rate significantly higher than was offered to a party not in direct competition with the actor.
- An actor files a patent infringement lawsuit against a developer without first offering to negotiate a license on RAND terms.

There are compelling reasons for this prohibition. In our experience, contractual and intellectual property rights are frequently used to extract rents for access to EHI or to prevent competition from developers of interoperable technologies and services (*see* section VIII.C.5.c.iv. of this preamble). These practices frustrate access, exchange, and use of EHI and stifle competition and innovation in the health IT sector. As a case in point, even following the enactment of the Cures Act, some EHR developers are selectively prohibiting—whether expressly or through commercially unreasonable terms—the disclosure or use of technical interoperability information required for third-party applications to be able to access, exchange, and use EHI maintained in EHR systems. This limits health care providers' use of the EHI maintained on their behalf to the particular capabilities and use cases that their EHR developer happens to support. More than this, by limiting the ability of providers to choose what applications and technologies they can use with their EHR systems, these practices close off the market to innovative applications and services that providers and other stakeholders need to deliver greater value and choice to health care purchasers and consumers.

Despite these serious concerns, we recognize that the definition of information blocking may be broader than necessary and could have unintended consequences. In contrast to the practices described above, we believe it is generally appropriate for actors to license their intellectual property (IP) on RAND terms that do not block interoperability. Provided certain conditions are met, we believe that these practices would further the goals of the information blocking provision by allowing actors to protect the value of their innovations and earn returns on the investments they have made to develop, maintain, and update those innovations. This in turn will protect future incentives to invest in, develop, and disseminate interoperable technologies and services. Conversely, if actors cannot (or believe they cannot) protect and commercialize their innovations, they may not engage in these productive activities that improve access, exchange, and use of EHI.

While we believe this exception is necessary to promote competition and consumer welfare, we are highly sensitive to the danger that actors will continue to use their contractual and IP rights to interfere with access, exchange, and use of EHI, undermining the information blocking provision's fundamental objectives. For this reason, the exception would be subject to strict conditions to ensure, among other things, that actors license interoperability elements on RAND terms and that they do not impose collateral terms or engage in other practices that would impede the use of the interoperability elements or otherwise undermine the intent of this exception.

We acknowledge that preventing intellectual property holders from extracting rents for access to EHI may differ from standard intellectual property policy. Absent specific circumstances, IP holders are generally free to negotiate with prospective licensees to determine the royalty to practice their IP, and this negotiated royalty frequently reflects the value the licensee would obtain from exercising those rights. However, in the context of EHI, we propose that a limitation on rents is essential due to the likelihood that rents will frustrate access, exchange, and use of EHI, particularly because of the power dynamics that exist in the health IT market.

We remind readers that actors are not required to seek the protection of this (or any other) exception. If an actor does not want to license a particular technology, it may choose to comply with the information blocking provision in another way, such as by developing and providing alternative means of accessing, exchanging, and using EHI that are similarly efficient and efficacious. The purpose of this exception is not to dictate a licensing scheme for all, or even most, health IT, but rather to provide a tailored ''safe harbor'' that will provide clear expectations for those who desire it.

i. Reasonable and Non-Discriminatory (RAND) Terms

We propose to require, as a condition of this exception, that any terms upon which an actor licenses interoperability elements must be reasonable and non-discriminatory (RAND). As discussed below, commitments to license technology on RAND terms are frequently required in the context of standards development organizations (SDOs), and we believe that the practical and policy considerations that have led SDOs to adopt these policies are related in many respects to the information blocking concerns presented when an actor exploits control over interoperability elements to extract economic rents or impede the development or use of interoperable technologies and services.

We recognize that strong legal protections for IP rights can promote competition and innovation.[125] Nevertheless, IP rights can also be misused in ways that undermine these goals.[126] We believe this potential for abuse is heightened when the IP rights pertain to functional aspects of technology that are essential to enabling interoperability. As an important example, a technology developer may encourage the inclusion of its technology in an industry standard created by an SDO while not disclosing that it has IP rights in that technology. After the SDO incorporates the technology into its standard, and industry begins to make investments tied to the standard, the IP-holder may then assert its IP rights and demand royalties or license terms that it could not have achieved before the standard was adopted because companies would incur substantial switching costs to abandon initial designs or adopt different products.[127] To address these

[125] *See* FTC and DOJ Antitrust Guidelines for the Licensing of Intellectual Property, at 2 (2017), *https://www.ftc.gov/system/files/documents/public_statements/1049793/ip_guidelines_2017.pdf.*

[126] *See Assessment Techs. of WI, LLC* v. *WIREdata, Inc.,* 350 F.3d 640, 644–45 (7th Cir. 2003); *Sega Enterprises Ltd.* v. *Accolade, Inc.,* 977 F.2d 1510, 1520–28 (9th Cir. 1992); *Sony Computer Entertainment, Inc.* v. *Connectix Corp.,* 203 F.3d 596, 602–08 (9th Cir. 2000); *Bateman* v. *Mnemonics, Inc.,* 79 F.3d 1532, 1539–40 n. 18 (11th Cir. 1996); *Atari Games Corp.* v. *Nintendo of America, Inc.,* 975 F.2d 832, 842–44 (Fed. Cir. 1992).

[127] *See* DOJ and FTC, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition, at 37–40 (Apr. 2017), *https://www.ftc.gov/sites/default/files/documents/reports/antitrust-enforcement-and-intellectual-property-rights-promoting-innovation-and-competition-report.s.department-justice-and-federal-trade-commission/p040101promotinginnovationandcompetitionrpt0704.pdf.*

types of concerns, while balancing the legitimate interests and incentives of IP owners, many SDOs now have policies requiring members who contribute technologies to a standard to voluntarily commit to license that technology on RAND terms and will consider whether firms have made voluntary RAND commitments when weighing whether to include their technology in standards.[128] While this commitment to license on RAND terms is voluntary as compared to our proposed requirement to use RAND terms, it serves to illustrate how RAND terms can be used to address such concerns.

Similar concerns arise when actors who control proprietary interoperability elements demand royalties or license terms from competitors or other persons who are technologically dependent on the use of those interoperability elements. As discussed in section VIII.C.5 of this preamble, to the extent that the interoperability elements are essential to enable the efficient access, exchange, or use of EHI by particular persons or for particular purposes, any practice by the actor that could impede the use of the interoperability elements for that purpose—or that could unnecessarily increase the cost or other burden of using the elements for that purpose—would give rise to an obvious risk of interference with access, exchange, or use of EHI under the information blocking provision.

We believe that a RAND requirement would balance the need for robust IP protections with the need to ensure that this proposed exception does not permit actors to exercise their IP or other proprietary rights in inappropriate ways that block the development, adoption, or use of interoperable technologies and services. The exercise of IP rights in these ways is incompatible with the information blocking provision, which protects the investments that taxpayers and the health care industry have made to adopt technologies that will enable the efficient sharing of EHI to benefit consumers and the health care system. While actors are entitled to protect and exercise their IP rights, to benefit from this exception to the information blocking provision they must do so in a reasonable and non-discriminatory manner that does not undermine these efforts and impede the appropriate flow of EHI.

Accordingly, we propose that, to qualify for this exception, an actor must license requested interoperability elements on RAND terms. To comply with this condition, any terms or conditions under which the actor discloses or allows the use of interoperability elements must meet several requirements set forth below. These requirements apply to both price terms (such as royalties and license fees) and other terms, such as conditions or limitations on access to interoperability elements or the purposes for which they can be used.

Responding To Requests

We propose that, upon receiving a request to license or use interoperability elements, an actor would be required to respond to the requestor within 10 business days from receipt of the request. We note that the request could be made to ''license'' or ''use'' the interoperability elements because a requestor may not always know that ''license'' is the legal mechanism for ''use'' when making the request. This provision is intended to ensure that a requestor is given an opportunity to license *and* use interoperability elements. As such, the requirement for responding to requests should not be limited to requests to ''license.''

In order to meet this requirement, the actor would be required to respond to the requestor within 10 business days from the receipt of the request by: (1) Negotiating with the requestor in a RAND fashion to identify the interoperability elements that are needed; and (2) offering an appropriate license with RAND terms, consistent with its other obligations under this exception. We emphasize that, in order to qualify for this proposed exception, the actor is only required to *negotiate* with the requestor in a RAND fashion and to *offer* a license with RAND terms. The actor is not required to *grant* a license in all instances. For example, the actor would not be required to grant a license if the requestor refuses an actor's offer to license interoperability elements on RAND terms.

We emphasize that there would be circumstances under which the actor could pursue legal action against parties that infringe its intellectual property whilst complying with this exception. For instance, an actor could bring legal action if a firm appropriates the actor's intellectual property without requesting a license or after refusing to accept a license on RAND terms.

We do not propose a set timeframe for when the negotiations must be resolved because it is difficult to predict the duration of such negotiations. For instance, there could be situations when the actor and requestor meet once and the actor makes a RAND offer that is immediately accepted by the requestor. However, there could be other situations when the requestor and actor each make counteroffers, which would extend the negotiations.

We request comment on whether 10 business days is an appropriate amount of time for the actor to respond to the requestor. In proposing this timeframe, we considered the urgency of certain requests to license interoperability elements and our expectation that developers would have standard licenses at their disposal that could be adapted in these situations. We considered proposing response timeframes ranging from 5 business days to 15 business days. We also considered proposing two separate timeframes for: (1) Negotiating with the requestor; and (2) offering the license. If commenters prefer a different response timeframe or approach than proposed, we request that commenters explain their rationale with as much detail as possible.

In addition, we query whether we should create set limits for: (1) The amount of time the requestor has to accept the actor's initial offer or make a counteroffer; (2) if the requestor makes a counteroffer, the amount of time the actor has to accept the requestor's counteroffer or make its own counteroffer; and (3) an allowable number of counteroffers in negotiations.

Scope of Rights

To qualify for this proposed exception, we propose that the actor must license the requested interoperability elements with all rights necessary to access and use the interoperability elements for the following purposes, as applicable:

- All rights necessary to access and use the interoperability elements for the purpose of developing products or services that are interoperable with the actor's health IT or with health IT under the actor's control and/or any third party who currently uses the actor's interoperability elements to interoperate with the actor's health IT or health IT under the actor's control. These rights would include the right to incorporate and use the interoperability elements in the licensee's own technology to the extent necessary to accomplish this purpose.
- All rights necessary to market, offer, and distribute the interoperable products and services described above to potential customers and users, including the right to copy or disclose the interoperability elements as necessary to accomplish this purpose.
- All rights necessary to enable the use of the interoperable products or services in production environments,

[128] *See, e.g., Microsoft Corp.* v. *Motorola, Inc.,* No. C10–1823JLR, 2013 WL 2111217, at *6 (W.D. Wash. Apr. 25, 2013).

including using the interoperability elements to access and enable the exchange and use of electronic health information.

We request comment on whether these rights are sufficiently inclusive to support licensees in developing interoperable technologies, bringing them to market, and deploying them for use in production environments. We also request comment on the breadth of these required rights and if they should be subject to any limitations that would not interfere with the uses we have described above.

Reasonable Royalty

As a condition of this exception, we propose that if an actor charges a royalty for the use of interoperability elements, the royalty base and rate must be reasonable. Consistent with the requirements for demonstrating that activities and practices meet the conditions of an exception proposed in section VIII.C.6.c, the actor would need to show that the royalty base was reasonable and that the royalty was within a reasonable range for the interoperability elements at issue. Importantly, we note that the reasonableness of any royalties would be assessed solely on basis of the independent value of the actor's technology to the licensee's product,[129] *not* on any strategic value stemming from the actor's control over essential means of accessing, exchanging, or using electronic health information. For instance, the reasonableness of royalties could not be assessed based on the strategic value stemming from the adoption of the technology by customers or users, the switching costs associated with the technology, or other circumstances of technological dependence described elsewhere in this preamble (see section VIII.C.5). We note that ''strategic value'' would stem from the actor's control over essential means of accessing, exchanging, or using electronic health information. Limiting a reasonable royalty to the value of the technology isolated from strategic value is similar in concept to apportionment of reasonable royalties for the infringement of standard essential patents (SEPs).[130] In our context, permitting an actor to charge a royalty on the basis of these considerations would effectively allow the actor to extract rents on access, exchange, and use of EHI, which is contrary to the goals of the information blocking provision.

In evaluating the actor's assertions and evidence that the royalty was reasonable, we propose that ONC may consider the following factors:

- The royalties received by the actor for the licensing of the proprietary elements in other circumstances comparable to RAND-licensing circumstances.
- The rates paid by the licensee for the use of other comparable proprietary elements.
- The nature and scope of the license.
- The effect of the proprietary elements in promoting sales of other products of the licensee and the licensor, taking into account only the contribution of the elements themselves and not of the enhanced interoperability that they enable.
- The utility and advantages of the actor's interoperability element over the existing technology, if any, that had been used to achieve a similar level of access, exchange, or use of EHI.
- The contribution of the elements to the technical capabilities of the licensee's products, taking into account only the value of the elements themselves and not the enhanced interoperability that they enable.
- The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the proprietary elements or analogous elements that are also covered by RAND commitments.
- The portion of the realizable profit that should be credited to the proprietary elements as distinguished from non-proprietary elements, the manufacturing process, business risks, significant features or improvements added by the licensee, or the strategic value resulting from the network effects, switching costs, or other effects of the adoption of the actor's technology.
- The opinion testimony of qualified experts.
- The amount that a licensor and a licensee would have agreed upon (at the time the licensee began using the elements) if both were considering the RAND obligation under this exception and its purposes, and had been reasonably and voluntarily trying to reach an agreement.

These factors mirror those used by courts that have examined the reasonableness of royalties charged pursuant to a commitment to an SDO to license standard-essential technologies on RAND terms (*see Microsoft Corp.* v. *Motorola, Inc.;*[131] In re *Innovatio IP Ventures, LLC Patent Litig.;*[132] and *Realtek Semiconductor Corp.* v. *LSI Corp*[133]). However, we have adapted the factors to the information blocking context as follows. In the SDO context, the RAND requirement mitigates the risk that patent-holders will engage in ''hold up''—that is, charging excessive royalties that do not reflect the value of their contributions to the standard, but rather reflect the costs associated with switching to alternative technologies after a standard is adopted—and that the cumulative effect of such royalties will make the standard too expensive to implement—a problem called ''royalty stacking.''[134] To address the risks of hold-up and royalty stacking in the standards development context, a RAND license should compensate a patentee for their technical contribution to the technology embodied in a standard, but should not compensate them for mere inclusion in the standard.

Similarly, in the context of information blocking, we propose the RAND inquiry focuses on whether the royalty demanded by the actor represents the independent value of the actor's proprietary technology. We propose that if the actor has licensed the interoperability element through a standards development organization in accordance with such organization's policies regarding the licensing of standards-essential technologies on reasonable and non-discriminatory terms, the actor may charge a royalty that is consistent with such policies. Rather than asking whether the royalty inappropriately captures additional value derived from the technology's inclusion in the industry standard, we would ask whether the actor is charging a royalty that is not based on the value of its technology (embodied in the interoperability elements) but rather includes the strategic value stemming from the adoption of that technology by customers or users. Thus, under this proposed approach and the factors set forth above, we would consider the technical contribution of the actor's interoperability elements to the licensee's products—such as any proprietary capabilities or features that the licensee uses in its product—but would screen out any functional aspects of the actor's technology that are used only to establish interoperability and enable EHI to be accessed, exchanged, and used. Additionally, we propose that

[129] *See Ericsson, Inc.* v. *D-Link Systems, Inc.,* 773 F.3d 1201, 1226; 1232 (Fed. Cir. 2014).

[130] *See, e.g., Georgia-Pacific Corp.* v. *United States Plywood Corp.,* 318 F. Supp 1116 (S.D.N.Y. 1970) (utilizing the more common approach).

[131] Case No. 10–cv–1823 JLR, 2013 WL 2111217 (W.D.Wash. Apr. 25, 2013).

[132] MDL 2303, 2013 WL 5593609 (N.D.Ill. Oct. 3, 2013).

[133] Case No. 5:12–cv–03451–RMW, 2014 WL 46997 (N.D.Cal. Jan. 6, 2014).

[134] *Microsoft Corp.* v. *Motorola, Inc.,* 864 F.Supp.2d 1023, 1027 (W.D.Wash. 2012).

to address the potential risk of royalty stacking we would need to consider the aggregate royalties that would apply if owners of other essential interoperability elements made royalty demands of the implementer. Specifically, we propose that, to qualify for this exception, the actor must grant licenses on terms that are objectively commercially reasonable taking into account the overall licensing situation, including the cost to the licensee of obtaining other interoperability elements that are important for the viability of the products for which it is seeking to license interoperability elements from the actor.

We clarify that, as proposed, this condition would not preclude an actor from licensing its interoperability elements pursuant to an existing RAND commitment to an SDO. We also note that, in addition to complying with the requirements described above, to meet this proposed condition any royalties charged must meet the condition, proposed separately below, that any license terms be non-discriminatory.

We request comment on these aspects of the proposed exception. Commenters are encouraged to consider, in particular, whether the factors and approach we have described will be administrable and appropriately balance the unreasonable blocking by actors of the use of essential interoperability elements with the need to provide adequate assurance to investors and innovators that they will be able to earn a reasonable return on their investments in interoperable technologies. If our proposed approach does not adequately balance these concerns or would not achieve our stated policy goals, we ask that commenters suggest revisions or alternative approaches. We ask that such comments be as detailed as possible and provide rigorous economic justifications for any suggested revisions or alternative approaches.

Non-Discriminatory Terms

We propose that for this exception to apply the terms on which an actor licenses and otherwise provides interoperability elements must be non-discriminatory. This requirement would apply to both price and non-price terms, and thus would apply to the royalty terms discussed immediately above as well as other types of terms that may be included in licensing agreements or other agreements related to the provision or use of interoperability elements.

To comply with this condition, the terms on which the actor licensed the interoperability elements must be based on criteria that the actor applied uniformly for all substantially similar or similarly situated classes of persons and requests. This requirement addresses a root cause of information blocking. In order to be considered non-discriminatory, such criteria would have to be objective and verifiable, not based on the actor's subjective judgment or discretion. We emphasize that this proposal does not mean that the actor must apply the same terms for all persons or classes of persons requesting a license. However, any differences in terms would have to be based on actual differences in the costs that the actor incurred or other reasonable and non-discriminatory criteria. Moreover, we propose that any criteria upon which an actor varies its terms or conditions would have to be both competitively neutral—meaning that the criteria are not based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using EHI obtained via the interoperability elements in a way that facilitates competition with the actor—and neutral as to the revenue or other value that the requestor may be derived from access, exchange, or use of the EHI obtained via the interoperability elements, including any secondary use of such EHI. We believe these limitations are necessary in light of the potential for actors to use their control over interoperability elements to engage in discriminatory practices that create unreasonable barriers or costs for persons seeking to develop, offer, or use interoperable technologies to expand access and enhance the exchange and use of EHI.

To clarify our expectations for this proposed condition, we provide the following illustration. Consider an EHR developer that establishes an ''app store'' through which third-party developers can license the EHR developer's proprietary APIs, which we assume are separate from the APIs required by the API Condition of Certification proposed in § 170.404. The EHR developer could charge a reasonable royalty and impose other reasonable terms to license these interoperability elements. The terms and conditions could vary based on neutral, objectively verifiable, and uniformly applied criteria. These might include, for example, significantly greater resources consumed by certain types of apps, such as those that export large volumes of data on a continuous basis, or the heightened risks associated with apps designed to ''write'' data to the EHR database or to run natively within the EHR's user interface. In contrast, the EHR developer could *not* vary its terms and conditions based on subjective criteria, such as whether it thinks an app will be ''popular'' or is a ''good fit'' for its ecosystem. Nor could it offer different terms or conditions on the basis of objective criteria that are not competitively neutral, such as whether an app ''connects to'' other technologies or services, provides capabilities that the EHR developer plans to incorporate in a future release of its technology, or enables an efficient means for customers to export data for use in other databases or technologies that compete directly with the EHR developer. Similarly, the EHR developer could not set different terms or conditions based on how much revenue or other value the app might generate from the information it collects through the APIs, such as by introducing a revenue-sharing requirement for apps that use data for secondary purposes that are very lucrative and for which the EHR developer would like a ''piece of the pie.'' Such practices would disqualify the actor from this exception and would implicate the information blocking provision.

The foregoing conditions are not intended to limit an actor's flexibility to set different terms based on legitimate differences in the costs to different classes of persons or in response to different classes of requests, so long as any such classification was in fact based on neutral criteria (in the sense described above) that are objectively verifiable and were applied in a consistent manner for persons and/or requests within each class. As an important example, the proposed condition would not preclude a covered actor from pursuing strategic partnerships, joint ventures, co-marketing agreements, cross-licensing agreements, and other similar types of commercial arrangements under which it provides more favorable terms than for other persons with whom it has a more arms-length relationship. In these instances the actor should have no difficulty identifying substantial and verifiable efficiencies that demonstrate that any variations in its terms and conditions were based on objective and neutral criteria. We do note an important caveat, however, specifically that a health IT developer of certified health IT who is an ''API Technology Supplier'' under the Condition of Certification proposed in § 170.404 would not be permitted to offer different terms in connection with the APIs required by that Condition of Certification. As discussed in section VII.B.4 of this preamble, we propose that API Technology Suppliers are

required to make these APIs available on terms that are no less favorable than provided to their own customers, suppliers, partners, and other persons with whom they have a business relationship. As noted below towards the end of our discussion of this exception to the information blocking provision, the exception incorporates the API Condition of Certification's requirements in full for all health IT developers subject to that condition.

We welcome comments on the foregoing condition and requirements.

Collateral Terms

We propose five additional conditions that would reinforce the requirements of this exception discussed above. These additional conditions would provide bright-line prohibitions for certain types of collateral terms or agreements that we believe are inherently likely to interfere with access, exchange, or use of EHI. We propose that any attempt to *require* a licensee or its agents or contractors to do or agree to do any of the following would disqualify the actor from this exception and would be suspect under the information blocking provision.

First, the actor must not require the licensee or its agents or contractors to not compete with the actor in any product, service, or market, including markets for goods and services, technologies, and research and development. We are aware that such agreements have been used to either directly exclude suppliers of interoperable technologies and services from the market or to create exclusivity that reduces the range of technologies and options available to health care providers and other health IT customers and users.

Second, and for similar reasons, the actor must not require the licensee or its agents or contractors to deal exclusively with the actor in any product, service, or market, including markets for goods and services, technologies, and research and development.

Third, the actor must not require the licensee or its agents or contractors to obtain additional licenses, products, or services that are not related to or can be unbundled from the requested interoperability elements. This condition reinforces the condition described earlier requiring that any royalties charged by the actor for the use of interoperability elements be reasonable. Without this condition, we believe that an actor could require a licensee to take a license to additional interoperability elements that the licensee does not need or want, which could enable the actor to extract royalties that are inconsistent with its RAND obligations under this exception. We clarify that this condition would not preclude an actor and a willing licensee from agreeing to such an arrangement, so long as the arrangement was not *required.*

Fourth, the actor must not condition the use of interoperability elements on a requirement or agreement to license, grant, assign, or transfer the licensee's own IP to the actor. We believe it is inconsistent with the actor's RAND licensing obligations under this exception, and would raise information blocking concerns, for an actor to use its control over interoperability elements as leverage to obtain a ''grant back'' of IP rights or other consideration whose value may exceed that of a reasonable royalty. Consistent with our approach under other conditions of this exception, this condition would not preclude an actor and a willing licensee from agreeing to a cross-licensing, co-marketing, or other agreement if they so choose. However, the actor cannot *require* the licensee to enter into such an agreement. The actor must offer the option of licensing the interoperability elements without a promise to provide consideration beyond a reasonable royalty. We note that in the SDO context, it can sometimes be consistent with RAND terms to require that an SEP licensee also grant a cross-license to any SEPs that it holds, provided that the cross-license is limited to patents essential to the licensed standard. In this way, this condition differs from licensing in the SDO context.

Finally, the actor must not condition the use of interoperability elements on a requirement or agreement to pay a fee of any kind whatsoever unless the fee meets either the narrowly crafted condition to this exception for a reasonable royalty, or, alternatively, the fee satisfies the separate exception proposed in § 171.204, which permits the recovery of certain costs reasonably incurred. As noted in section VIII.D.4, that exception generally does not allow for the recovery of royalties or other fees associated with intangible assets. However, the exception does allow for the reasonable and actual development and acquisition costs of such assets.

We request comment on the categorical exclusions outlined above. In particular, we encourage commenters to weigh in on our assumption that these practices are inherently likely to interfere with access, exchange, or use of EHI. We also encourage commenters to suggest any conceivable benefits that these practices might offer for interoperability or for competition and consumers that we might have overlooked. Again, we ask that to the extent possible commenters provide detailed economic rationale in support of their comments.

Non-Disclosure Agreement

We propose that an actor would be permitted under this exception to require a licensee to agree to a confidentiality or non-disclosure agreement (NDA) to protect the actor's trade secrets, provided that the NDA is no broader than necessary to prevent the unauthorized disclosure of the actor's trade secrets. Further, we propose that the actor would have to identify (in the NDA) the specific information that it claims as trade secrets, and that such information would have to meet definition of a trade secret under applicable law. We believe these safeguards are necessary to ensure that the NDA is not used to impose restrictions or burdensome requirements that are not actually necessary to protect the actor's trade secrets and that impede the use of the interoperability elements. The use of an NDA for such purposes would preclude an actor from qualifying for this exception and would implicate the information blocking provision. We note that if the actor is a health IT developer of certified health IT, it may be subject to the Condition of Certification proposed in § 170.403, which prohibits certain health IT developer prohibitions and restrictions on communications about a health IT developer's technology and business practices. This exception would not in any way abrogate the developer's obligations to comply with that condition.

We encourage comment on this condition of the proposed exception.

ii. Additional Requirements Relating to the Provision of Interoperability Elements

In addition to the conditions described above, we propose that an actor's practice would need to comply with additional conditions that ensure that actors who license interoperability elements on RAND terms do not engage in separate practices that impede the use of those elements or otherwise undermine the intent of this exception. These conditions are analogous to the conditions described in our proposal above concerning collateral terms but address a broader range of practices that may not be effected through the license agreements themselves or that occur separately from the licensing negotiations and other dealings between the actor and the licensee. Specifically, we propose that an actor would not qualify for this exception if it engaged in a practice that had the purpose or

effect of impeding the efficient use of the interoperability elements to access, exchange, or use EHI for any permissible purpose; or the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand. As an illustration, the exception would not apply if the developer licensed its proprietary APIs for use by third-party apps but then prevented or delayed the use of those apps in production environments by, for example, restricting or discouraging customers from enabling the use of the apps, or engaging in ''gate keeping'' practices, such as requiring apps to go through a vetting process and then applying that process in a discriminatory or unreasonable manner.

Finally, to ensure the actor's commitments under this exception are durable, we propose one additional safeguard: An actor cannot avail itself of this exception if, having licensed the interoperability elements, the actor makes changes to the elements or its technology that ''break'' compatibility or otherwise degrade the performance or interoperability of the licensee's products or services. We believe this condition is crucial given the ease with which an actor could make subtle ''tweaks'' to its technology or related services that could disrupt the use of the licensee's compatible technologies or services and result in substantial competitive and consumer injury.

We clarify and emphasize that this proposed condition would in *no way* prevent an actor from making improvements to its technology or responding to the needs of its own customers or users. However, to benefit from the exception, the actor's practice would need to be necessary to accomplish these purposes and the actor must have afforded the licensee a reasonable opportunity under the circumstances to update its technology to maintain interoperability. We also recognize that an actor may have to suspend access or make other changes immediately and without prior notice in response to legitimate privacy, security, or patient safety-related exigencies. Such practices would be governed by the exceptions proposed in section VIII.D of this preamble and thus would not need to qualify for this exception.

iii. Compliance With Conditions of Certification

As a final condition of this proposed exception, we propose that health IT developers of certified health IT who are subject to the Conditions of Certification proposed in §§ 170.402, 170.403, and 170.404 must comply with all requirements of those Conditions of Certification for all practices and at all relevant times. Several of the requirements of these conditions mirror those of this exception. However, in some instances the Conditions of Certification provide additional or more specific requirements that apply to the provision of interoperability elements by developers of certified health IT. For example, developers subject to the API Condition of Certification must make certain public APIs available on terms that are royalty free and no less favorable than provided to themselves and their customers, suppliers, partners, and other persons with whom they have a business relationship. These more prescriptive requirements reflect the specific obligations of health IT developers under the Program, including the duty to facilitate the access, exchange, and use of information from patients' electronic health records without special effort. A health IT developer of certified health IT's failure to comply with these and other certification requirements that specifically support interoperability would, in addition to precluding the developer from invoking this exception, be significant evidence of information blocking.

7. Maintaining and Improving Health IT Performance

We propose to establish an exception to the information blocking provision for certain practices that are reasonable and necessary to maintain and improve the overall performance of health IT, provided certain conditions are met. The proposed exception would recognize as reasonable and necessary the practice of an actor making health IT under its control temporarily unavailable to maintain or improve the health IT. The exception and corresponding conditions are set forth in the proposed regulation text in § 171.207.

EHI should be accessible and usable on demand by those that need it. However, in order for this to happen, the health IT through which EHI is accessed, exchanged, or used must perform properly and efficiently. This requires that health IT be maintained and in some instances improved. The performance of such maintenance and improvements sometimes requires that health IT is temporarily taken offline, which can interfere with the access, exchange, and use of EHI. We believe this exception is necessary to ensure that actors are not deterred from maintaining and improving the overall performance of health IT because temporary unavailability of EHI may cause interference with its access, exchange, and use. Without this specific exception, there could be a significant risk that actors may refrain from conducting maintenance and improvements of health IT out of fear that if the purpose was not for preventing harm, promoting security, or for another reason covered by the other exceptions, then their actions might contravene the information blocking provision.

This exception would apply to the unavailability of health IT occasioned by both planned and unplanned maintenance and improvements. Planned maintenance or improvements are typically carried out at regular intervals and address routine repairs, updates, or new releases. Unplanned maintenance or improvements respond to urgent or time-sensitive issues, which cannot wait for the occurrence of a pre-planned time period to implement the required maintenance or improvements.

This proposed exception acknowledges that the performance of health IT is often measured by service level agreements that provide flexibility to ensure that system availability is balanced with essential maintenance and improvements. Where the provision of health IT is subject to an allowance for maintenance or improvement that has been agreed to by the recipient of that health IT, we propose that neither that agreement, nor the performance of it, should constitute information blocking, provided that certain conditions are met.

To ensure that the actor's practice of making health IT, and in turn EHI, unavailable for the purpose of carrying out maintenance or improvements is reasonable and necessary, we have identified conditions that must be satisfied at all relevant times to qualify for this exception.

Unavailability of Health IT Must Be for no Longer Than Necessary To Achieve the Maintenance or Improvements for Which the Health IT was Made Unavailable

Any unavailability of health IT must be for a period of time no longer than necessary to achieve the maintenance or improvement purpose for which the health IT is made unavailable. This condition recognizes the critical importance of access to EHI and ensures that health IT is not made unavailable for longer than needed. For example, a health IT developer of certified health IT that has the right under its contract with a large health system to take its system offline for four hours each month to conduct routine maintenance would not qualify for this exception if

an information blocking claim was made about a period of unavailability during which no maintenance was performed.

Making this evaluation for unplanned maintenance or improvements will be more difficult, because unplanned maintenance or improvements are typically initiated in response to a threat or risk that needs to be responded to on an urgent basis and for so long as the threat or risk persists. However, if, for example, an HIE identified a software failure (not identified as a safety or security risk) that required immediate remediation necessitating the actor take its health IT offline, the actor would be expected to bring the health IT back online as soon as possible after the issue was resolved.

Unavailability of Health IT for Maintenance or Improvements Must Be Implemented in a Consistent and Non-Discriminatory Manner

We propose that any unavailability of health IT occasioned by the conduct of maintenance or improvements must be implemented in a consistent and non-discriminatory manner. This condition provides a basic assurance that when health IT is made unavailable for the purpose of performing maintenance or improvements that the unavailability is not abused by the actor that controls the health IT. For example, a health IT developer of certified health IT would not qualify for this exception if the developer, using a standard contract that provided a flexible allowance for planned maintenance or improvements, initiated planned maintenance or improvements for a customer with an expiring health IT contract during a time when users might reasonably be expected to access EHI, but conducted planned maintenance or improvements for new customers in the middle of the night. However, this condition does not require that actors conduct planned maintenance or improvements simultaneously, or require that every health IT contract provide the same promises in regard to planned maintenance or improvements. Indeed, a recipient of health IT may agree to a longer window for unavailability in exchange for a reduced fee for system maintenance, which would not contravene this condition.

Unavailability of Health IT for Maintenance or Improvements Must Be Agreed

In order to benefit from this exception, we propose that the unavailability of health IT due to maintenance or improvements initiated by a health IT developer of certified health IT, HIE, or HIN, must be agreed to by the individual or entity to whom the health IT is supplied. The availability of health IT is typically addressed in a written contract or other written agreements, that puts the recipient of the health IT on notice about the level of EHI and health IT unavailability that can be expected for users of the health IT. By such agreements, the recipient of the health IT willfully agrees to that level of planned and unplanned unavailability (typically referred to in health IT contracts as ''downtime''). Some health IT contracts address the question of system availability by way of an ''uptime warranty'' that specifies the maximum amount of unavailability for a specified period and the timing of any planned unavailability.

We acknowledge that in some cases, health IT needs to be taken offline or maintenance or improvements on an urgent basis and in a way that is not expressly permitted under a health IT contract. An actor may still satisfy this proposed condition so long as the maintenance or improvements are agreed to by the recipient of the health IT. This could be achieved by way of an oral agreement reached between the parties by telephone, but we note that because an actor must demonstrate that it satisfies the requirements of this exception, it would be best practice for an actor to ensure the agreement was in writing or, at minimum, contemporaneously documented.

This proposed condition of this exception only applies when the unavailability of health IT is caused by a health IT developer of certified health IT, HIE, or HIN. In these circumstances, it is the supplier of the health IT that controls if and when health IT is intentionally taken offline for maintenance or improvements. This condition does not apply when health IT is made unavailable for maintenance or improvements at the initiative of a recipient (or customer) of health IT, because in that case, the unavailability has, for the purpose of this exception, nothing to do with the supplier. When it is a customer of health IT that initiates unavailability, the unavailability would not need to be the subject of an agreement with the supplier of that health IT, nor anyone else, in order for the customer of health IT to benefit from this exception. For example, a health care provider that locally hosts and maintains its health IT (being software supplied by a health IT developer) would not need to satisfy this condition if it interfered with access to EHI by taking the health IT offline temporarily to conduct maintenance. However, if the same health care provider was to receive a new release of the health IT developer's software, which was to be implemented by the developer and which required that the health IT be taken offline by the developer for 6 hours, then that unavailability, or an allowance for it, would need to be the subject of prior agreement. Unavailability of health IT initiated by a recipient of health IT (rather than the supplier of the health IT) would still need to satisfy the other conditions of this exception, including that the unavailability be for a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable.

We note that this condition would need to be satisfied by any HIE or HIN that sought to benefit from this exception in connection with any interference with access, exchange, or use occasioned by an HIE or HIN making its health IT unavailable for the purposes of conducting maintenance or improvements. An HIE would need to have secured the agreement of those individuals or entities that use its exchange services, and a HIN would need to have obtained the agreement of the network's participants.

Interaction With Preventing Harm and Promoting Security Exceptions

When health IT is made unavailable for maintenance or improvements aimed at preventing harm to a patient or other person, or securing EHI, an actor must comply with the conditions specified in proposed § 171.201 or § 171.203 respectively, in order to qualify for an exception to the information blocking provision. This condition ensures that this exception cannot be used to avoid compliance with conditions applicable under other exceptions. For example, if part of an EHR system was taken offline in response to a health IT developer of certified health IT being alerted to the risk of corrupt or inaccurate data being recorded or incorporated in a patient's health record, any decision to make the EHR unavailable on this basis to conduct unplanned maintenance or improvements would need to accord with the conditions of the proposed exception for preventing harm (see § 171.201 and section VIII.D.1 of this proposed rule). Similarly, unavailability occasioned by maintenance or improvements initiated to secure EHI in response to a suspected malware attack would need to either be implemented in accordance with the actor's organizational security policy that satisfied the requirements of the proposed exception for promoting the

security of EHI or if the practice did not implement an organizational security policy, the actor must have made a determination in each case, based on the particularized facts and circumstances, consistent with the requirements of the exception (see § 171.203(d) and section VIII.D.3 of this proposed rule).

Request for Comment

We seek comment on this exception generally. Specifically, we seek comment on whether the proposed conditions impose appropriate limitations on actor-initiated health IT maintenance or improvements that lead to EHI unavailability. Our goal is to ensure that the exception is not abused, while at the same time recognizing reasonable commercial arrangements entered into by parties for the proper maintenance and improvement of health IT.

We are also considering whether to expand this exception to capture a broader class of practices that are the subject of reasonable commercial agreements and which, in the absence of an exception, may be considered information blocking. That is, to extend this exception or create new exceptions for additional types of practices that interfere with access, exchange, or use of EHI, but that are the subject of free agreement and which are reasonable and necessary. For example, we are considering whether a practice taken by an actor to throttle or meter the availability or performance of health IT, where agreed to by the recipient of that health IT, could ever be a practice that we recognize as not being information blocking if such practice does not otherwise qualify under an existing exception.

As discussed in section VIII.C.5 of this preamble, we are aware that actors can use commercial agreements to materially discourage, and in some instances outright prohibit, certain instances of access, exchange, or use of EHI. For example, a HIN might use a participation agreement to prohibit entities that receive EHI through the HIN from transmitting that EHI to entities who are not participants of the HIN. Such an arrangement would not be reasonable or necessary because there is no legitimate justification for it. However, we are also aware of commercial arrangements that are not motivated by anti-competitive considerations but that nonetheless have the effect of interfering with the access, exchange, or use of EHI. For example, a health IT developer of certified health IT may agree to commercial terms with a customer that have the effect of interfering with access, exchange, or use of EHI, but which are designed to appropriately accommodate the customer's limited resources, or to assure the performance of certain health IT functionality.

We expect that most reasonable and necessary commercial arrangements that affect access, exchange, or use of EHI could be recognized under one or more of the existing exceptions. However, we seek comment on whether there exists a class of legitimate commercial arrangements that could implicate the information blocking provision, but which would not benefit from the existing proposed exceptions.

E. Additional Exceptions—Request for Information

1. Exception for Complying With Common Agreement for Trusted Exchange

To support full network-to-network exchange of EHI, section 3001(c)(9)(A) of the PHSA, added by section 4003 of the Cures Act, directs the National Coordinator to convene public-private partnerships to develop or support a trusted exchange framework (Trusted Exchange Framework), including a common agreement for a common set of rules for trusted exchange between HINs (Common Agreement). The most recent draft Trusted Exchange Framework was released for public comment on January 5, 2018,[135] however, a new draft will be released in the coming months.

We are considering whether we would should propose, in a future rulemaking, a narrow exception to the information blocking provision for practices that are necessary to comply with the requirements of the Common Agreement. Such an exception may support adoption of the Common Agreement and encourage other entities to participate in trusted exchange through HINs that enter into the Common Agreement. It would do so by providing protection if there are practices that are expressly required by the Common Agreement, or that are necessary to implement such requirements, that might implicate the information blocking provision and would not qualify for another exception. We note that such an exception would be consistent with the complementary roles of the information blocking provision and other provisions of the Cures Act that support interoperability and enhance the trusted exchange of EHI (including the interoperable network exchange provisions at section 3001(c)(9) of the PHSA, the definition of interoperability at section 3000(10) of the PHSA, and the conditions of certification required by section 3001(c)(5)(D) of the PHSA).

We expect that any proposal would be narrowly framed such that contract terms, policies, or other practices that are not strictly necessary to comply with the Common Agreement would not qualify for the exception. Similarly, we expect that the proposal would provide that an actor could benefit from this exception only if the practice or practices that the actor pursued were no broader than necessary under the circumstances. These limitations would ensure that the exception is narrowly tailored to practices that are most likely to promote trusted exchange without unnecessarily impeding access, exchange, or use of EHI.

We ask commenters to provide feedback on this potential exception to the information blocking provision to be considered for inclusion in future rulemaking. Commenters should consider whether such an exception is necessary, given the scope of the other exceptions proposed in this NPRM, and whether there could be any negative effects of such an exception. We ask commenters to consider the appropriate scope of this exception, which could include which actors could benefit from the exception and the conditions that should apply in order to qualify for the exception.

2. New Exceptions

We welcome comment on any potential new exceptions we should consider for future rulemaking. Commenters should consider the policy goals and structure of the proposed exceptions in this proposed rule when providing comment. We ask that commenters provide rationale for any proffered exceptions to the information blocking provisions and any conditions an actor would need to meet to qualify for the proffered exception.

F. Complaint Process

Section 3022(d)(3)(A) of the PHSA directs the National Coordinator to implement a standardized process for the public to submit reports on claims of health information blocking. Such reports could be submitted regarding any practice by health care providers, health IT developers, exchanges, or networks that may constitute information blocking under section 3022(a). These practices include, but are not limited to, health IT products or developers of such products (or other entities offering such products to health care providers) not being interoperable or resulting in information blocking;

[135] ONC, *Draft Trusted Exchange Framework, https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf.*

and false statements by developers of certified health IT that they have not engaged in information blocking. Section 3022(d)(3)(B) further requires that this complaint process provide for the collection of such information as the originating institution, location, type of transaction, system and version, timestamp, terminating institution, locations, system and version, failure notice, and other related information.

We intend to implement and evolve this complaint process by building on existing mechanisms, including the complaint process currently available at *https://www.healthit.gov/healthit-feedback.* However, we request comment on this approach and any alternative approaches that would best effectuate this aspect of the Cures Act. In addition to any other comments that the public may wish to submit, we specifically request comment on the following issues:

- What types of information are most important to collect in order to identify potential instances of information blocking?
- What types of information are contemplated by the following categories delineated in section 3022(d)(3)(B): The originating institution; location; type of transaction; system and version; timestamp; terminating institution; locations; system and version; failure notice; and other related information?
- What types of information or data elements should be collected under each of the above categories?
- What additional types of information beyond the above may be relevant to complaints and allegations of information blocking, especially practices that involve contractual or other business practices for which some of the categories of technical or transactional information above may not apply?
- How can ONC encourage and streamline the collection of such information so as to minimize burden and encourage the submission of complaints, especially complaints about practices that raise the types of information blocking concerns described in this proposed rule?
- How can ONC facilitate the inclusion of sufficient detail and granularity in complaints to enable effective investigations?
- What safeguards should be provided to support adequate confidentiality and handling of information that could: (1) Identify the source of the complaint or allegation; (2) contain other individually identifiable information; and (3) contain confidential or proprietary business information?

G. Disincentives for Health Care Providers—Request for Information

Section 3022(b)(2)(B) of the PHSA provides that any health care provider determined by the OIG to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable federal law, as the Secretary sets forth through notice and comment rulemaking. However, we note that these disincentives may not cover the full range of conduct within the scope of section 3022(a)(1). We request information on disincentives or if modifying disincentives already available under existing HHS programs and regulations would provide for more effective deterrents.

We also seek information on the implementation of section 3022(d)(4) of the PHSA, which provides that in carrying out section 3022(d) of the PHSA, the Secretary shall, to the extent possible, not duplicate penalty structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before December 13, 2016—enactment of the Cures Act.

IX. Registries Request for Information

Section 4005 (a) and (b) of the Cures Act focuses on interoperability and bidirectional exchange between EHRs and registries, including clinician-led clinical data registries. ONC is approaching these provisions from several angles to address the technical capability of EHRs to exchange data with registries in accordance with applicable recognized standards. Based on stakeholder engagement and public comments on prior ONC regulations, we have identified a wide range of areas where the use of standards could significantly improve bidirectional exchange with registries for a range of purposes, including public health, quality reporting, and care quality improvement.

As discussed in the ''Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs'' draft report released by ONC for public comment in December of 2018,[136] health care providers are faced with a myriad of federal public health reporting requirements and options that rely on both bidirectional exchange and aggregation of clinical data. CDC, SAMHSA, FDA, HRSA, and USDA also fund state and local public health jurisdictions to collect clinical data from health care providers. As noted in the Cures Act, there are also a wide range of clinician-led quality and specialty clinical data registries. Compounding these reporting requirements and options is, as reported by health care providers, a lack of standardization across electronic infrastructure that has led to a comparatively slow adoption of health IT systems among registries. This lack of interoperability impacts not only data exchange between health care providers, but is a significant barrier to the integration and potential use of clinical data received from a registry for quality improvement or clinical care.

For these reasons outlined above, we believe it is appropriate to explore multiple approaches to advancing health IT interoperability for bidirectional exchange with registries in order to mitigate risks based on factors like feasibility and readiness, potential unintended burden on health care providers, and the need to focus on priority clinical use cases. ONC is in the process of conducting research and analysis to determine what evidence-based use cases should be supported and what standards are available to support such use cases. We are also considering the overall maturity of technology adoption within the market to support identified standards and the use of certified EHRs and clinical data registries for these identified use cases in the near term, as well as identifying glide paths for the potential future development of enterprise solutions.

In the 2015 Edition final rule, we included certification criteria and standards that are applicable for specific use cases for bidirectional exchange such as Immunization Information Systems. In this proposed rule, we have proposed processes for updating standards as well as new policies related to real world testing that would help ensure that functionalities are implemented in a manner that is technically feasible in a practice setting. In addition, we have worked with federal partners to advance health IT policies related to bidirectional exchange with registries in a manner that supports and reflects the current market place while encouraging innovation and increased adoption. For example, we have worked with CMS to enhance guidance for QCDRs under the MIPS to support health IT innovation and partnership with health IT organizations. We are also working with the CDC and states to support enhancements to PDMP integration as a

[136] *https://www.healthit.gov/topic/usability-and-provider-burden/strategy-reducing-burden-relating-use-health-it-and-ehrs.*

priority use case for standards-based health IT solutions. We believe these efforts can help to address the near term need to support high priority use cases for bidirectional exchange between health care providers and registries.

In this proposed rule, we propose to adopt new standards and capabilities for certified APIs that have the potential to change how certain types of information exchange are done, including the potential to exchange information with clinical data and public health registries. In this request for information (RFI), we are seeking information on how health IT solutions and the proposals throughout this rule can aid bidirectional exchange with registries for a wide range public health, quality reporting, and clinical quality improvement initiatives. For example, in December of 2018, in the ''Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs'' draft report, we noted that HL7 was working on an update to the FHIR standard to support API access to request data on populations of patients, which could potentially address additional use cases, including supporting payer needs, public health and quality improvement efforts, and health research organizations. As discussed in section VII.4, FHIR Release 4 has now been published [85] and updated associated implementation specifications are expected to follow. FHIR Release 4 has several key improvements, including certain foundational aspects in the standard and ''FHIR resources'' designated as ''normative'' for the first time. This will lead to a cycle of more mature US FHIR Core profiles aligned with Release 4 and additional implementation guidance that explicitly specifies how to handle populations of patient data (batch exports) via FHIR to more efficiently enable population and learning health system-oriented services.

We seek comment on use cases where an API using FHIR Release 4 might support improved exchange between a provider and a registry. Specifically, we seek comment on how the use of this standard might:

- Reduce the burden of implementing multiple solutions for various types of exchange, while still supporting the variability needed to exchange information with registries devoted to the care of a population defined by a particular disease, condition, exposure, or therapy;
- Allow for the collection of detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures;
- Support an overall approach to data quality, including the systematic collection of clinical and other health care data, using standardized data elements and procedures to verify the completeness and validity of those data;
- Improve and enhance the ability of providers to leverage feedback from a registry to improve patient care; and
- Address a sufficiently wide range of use cases to warrant the prioritization of technical innovation on API-based options over the continued development of use-case-specific solutions in future rulemaking.

We also welcome any other comments stakeholders may have on implementation of the registries provisions under section 4005 of the Cures Act.

X. Patient Matching Request for Information

Patient matching is a critical component to interoperability and the nation's health information technology infrastructure. Accurate patient matching helps health care providers access and share the right information on the right patient when and where it is needed.

Inaccurate patient matching can compromise safety, privacy, and lead to increased health care costs, as acknowledged in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill, 2017: [137]

> The Committee is aware that one of the most significant challenges inhibiting the safe and secure electronic exchange of health information is the lack of a consistent patient data matching strategy. With the passage of the HITECH Act, a clear mandate was placed on the Nation's healthcare community to adopt electronic health records and health exchange capability. Although the Committee continues to carry a prohibition against HHS using funds to promulgate or adopt any final standard providing for the assignment of a unique health identifier for an individual until such activity is authorized, the Committee notes that this limitation does not prohibit HHS from examining the issues around patient matching. Accordingly, the Committee encourages the Secretary, acting through the Office of the National Coordinator for Health Information Technology and CMS, to provide technical assistance to private-sector led initiatives to develop a coordinated national strategy that will promote patient safety by accurately identifying patients to their health information.

Similarly, the Fiscal Year 2018 Appropriations Bill [138] also included language regarding patient matching.

> The Committee is aware that a challenge inhibiting the safe and secure electronic exchange of health information is the lack of a consistent approach to matching patient data. The Committee encourages ONC to engage with stakeholders on private-sector led initiatives to develop a coordinated strategy that will promote patient safety by accurately identifying patients to their health information.

Section 4007 of the 21st Century Cures Act (Pub. L. 114–255) directs the Government Accountability Office (GAO) to conduct a study on patient matching. Specifically, the GAO was charged to review the policies and activities of the Office of the National Coordinator for Health Information Technology (ONC) and other relevant stakeholders, including standards development organizations, developers, providers, suppliers, payers, quality organizations, States, health information technology policy and technical experts, and other appropriate entities. The GAO report, *Approaches and Challenges to Electronically Matching Patients' Records across Providers,* was released in January 2019.[139] In this report, GAO describes (1) stakeholders' patient record matching approaches and related challenges; and (2) efforts to improve patient record matching identified by stakeholders. Stakeholders said more could be done to improve patient record matching, and identified several efforts that could improve matching. For example, some said that implementing common standards for recording demographic data; sharing best practices and other resources; and developing a public-private collaboration effort could each improve matching. Stakeholders' views varied on the roles ONC and others should play in these efforts and the extent to which the efforts would improve matching. Multiple stakeholders emphasized that no single effort would solve the challenge of patient record matching.

Patient matching may be defined as the linking of one patient's data within and across health care providers in order to obtain a comprehensive and longitudinal view of that patient's health care. At a minimum, this is accomplished by linking multiple demographic data fields such as name, birth date, sex, phone number, and

[137] *https://www.congress.gov/114/crpt/hrpt699/CRPT-114hrpt699.pdf.*

[138] *https://appropriations.house.gov/uploadedfiles/23920.pdf.*

[139] U.S. Government Accountability Office, *Approaches and Challenges to Electronically Matching Patients' Records across Providers,* GAO–19–197, *https://www.gao.gov/assets/700/696426.pdf.*

address. For this reason, accurate and standardized data capture and exchange and optimized algorithm performance are critical components to the accurate patient matching. With this in mind, ONC has taken several steps to better understand the patient matching landscape and to identify areas where ONC can assist in standards and technical development, coordination, and innovation. For example, in 2017, ONC launched the Patient Matching Algorithm Challenge, where six winners were awarded total prize winnings of $75,000.[140] The goals of this challenge were to bring about greater transparency and data on the performance of existing patient matching algorithms, spur the adoption of performance metrics for patient matching algorithm developers, and positively impact other aspects of patient matching such as deduplication and linking. In addition, in 2018, ONC showcased innovative technical and non-technical approaches to matching through hosting a patient matching track at ONC's Second Interoperability Forum.[141]

In this Request for Information (RFI), we seek comment on additional opportunities that may exist in the patient matching space and ways that ONC can lead and contribute to coordination efforts with respect to patient matching. ONC and CMS collaborated to jointly issue complementary requests for information regarding patient matching. ONC is particularly interested in ways that patient matching can facilitate improved patient safety, better care coordination, and advanced interoperability. Inaccurate patient matching can lead to inappropriate and unnecessary care; unnecessary burden on both patients and providers to correct misidentification, time consuming and expensive burden on health systems to detect and reconcile duplicate patient records and improper record merges; and poor oversite into fraud and abuse. Per a survey by the College of Healthcare Information Management Executives, one in five providers named lack of an appropriate patient matching strategy as the primary reason for inadvertent illness or injury.[142] We consider this a quality of care and patient safety issue and seek stakeholder input on creative, innovative, and effective approaches to patient matching within and across providers. We also intend to review the responses to this RFI in concert with the GAO report once published.

We specifically seek input on the following:

- It is a common misconception that technology alone can solve the problem of poor data quality, but even the most advanced, innovative technical approaches are unable to overcome data quality issues. Thus, we seek input on the potential effect that data collection standards may have on the quality of health data that is captured and stored and the impact that such standards may have on accurate patient matching. We also seek input on other solutions that may increase the likelihood of accurate data capture, including the implementation of technology that supports the verification and authentication of certain demographic data elements such as mailing address, as well as other efforts that support ongoing data quality improvement efforts.
- In concert with the GAO study referenced above, we seek input on what additional data elements could be defined to assist in patient matching as well as input on a required minimum set of elements that need to be collected and exchanged. We encourage stakeholders to review the Patient Demographic Record Matching section of the Interoperability Standards Advisory[143] and comment on the standards and implementation specifications outlined. Public comments and subject matter feedback on all sections of the Interoperability Standards Advisory are accepted year round.
- Also in alignment with the GAO study, we seek input on whether and what requirements for electronic health records could be established to assure data used for patient matching is collected accurately and completely for every patient. For instance, the adopted 2015 Edition ''transitions of care'' certification criterion (§ 170.315(b)(1)) currently includes patient matching requirements for first name, last name, previous name, middle name, suffix, date of birth, address, phone number, and sex. These requirement also include format constraints for some of the data.
- There are unique matching issues related to pediatrics and we seek comment on innovative and effective technical or non-technical approaches that could support accurate pediatric record matching.
- Recent research suggests that involving patients in patient matching may be a viable and effective solution to increase the accuracy of matching, and giving patients access to their own clinical information empowers engagements and improved health outcomes. We seek comment on potential solutions that include patients through a variety of methods and technical platforms in the capture, update and maintenance of their own demographic and health data, including privacy criteria and the role of providers as educators and advocates.
- In addition, we seek input on standardized metrics for the performance evaluation of available patient matching algorithms. Health IT developers are each relying on a number of patient matching algorithms, however, without the adoption of agreed upon metrics for the evaluation of algorithm performance across the industry, existing matching approaches cannot be accurately evaluated or compared across systems or over time.
- At the same time, we seek input on transparent patient matching indicators such as database duplicate rate, duplicate creation rate, and true match rate, for example, that are necessary for assessment and reporting. The current lack of consensus, adoption, and transparency of such indicators makes communication, reporting, and cross-provider or cross-organizational comparisons impossible, impedes a full and accurate assessment of the extent of the problem, prohibits informed decision making, limits research on complementary matching methods, and inhibits progress and innovation in this area.
- There are a number of emerging private-sector led approaches in patient matching that may prove to be effective, and we seek input on these approaches, in general. A number of matching services that leverage referential matching technology have emerged in the market recently, yet evaluations of this type of approach has either not been conducted or has not been made public. Other innovative technical approaches such as biometrics, machine learning and artificial intelligence, or locally developed unique identifier efforts, when used in combination with non-technical approaches such as patient engagement, supportive policies, data governance, and ongoing data quality improvement efforts may enhance capacity for matching.
- Finally, ONC seeks input on new data that could be added to the United States Core Data for Interoperability (USCDI) or further constrained within it in order to support patient matching.

[140] *https://www.hhs.gov/about/news/2017/11/08/hhs-names-patient-matching-algorithm-challenge-winners.html.*

[141] *https://www.healthit.gov/news/events/oncs-2nd-interoperability-forum.*

[142] *https://chimecentral.org/wp-content/uploads/2014/11/Summary_of_CHIME_Survey_on_Patient_Data.pdf.*

[143] *https://www.healthit.gov/isa/patient-demographic-record-matching.*

XI. Incorporation by Reference

The Office of the Federal Register has established requirements for materials (*e.g.,* standards and implementation specifications) that agencies propose to incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5(a)). Specifically, § 51.5(a) requires agencies to discuss, in the preamble of a proposed rule, the ways that the materials it proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties; and summarize, in the preamble of the proposed rule, the material it proposes to incorporate by reference.

To make the materials we intend to incorporate by reference reasonably available, we provide a uniform resource locator (URL) for the standards and implementation specifications. In many cases, these standards and implementation specifications are directly accessible through the URLs provided. In instances where they are not directly available, we note the steps and requirements necessary to gain access to the standard or implementation specification. In most of these instances, access to the standard or implementation specification can be gained through no-cost (monetary) participation, subscription, or membership with the applicable standards developing organization (SDO) or custodial organization. In certain instances, where noted, access requires a fee or paid membership. As an alternative, a copy of the standards may be viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201. Please call (202) 690–7171 in advance to arrange inspection.

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A–119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. As discussed in section IV of this preamble, we have followed the NTTAA and OMB Circular A–119 in proposing standards and implementation specifications for adoption, including describing any exceptions in the proposed adoption of standards and implementation specifications. Over the years of adopting standards and implementation specifications for certification, we have worked with SDOs, such as HL7, to make the standards we propose to adopt, and subsequently adopt and incorporate by reference in the **Federal Register**, available to interested stakeholders. As described above, this includes making the standards and implementation specifications available through no-cost memberships and no-cost subscriptions.

As required by § 51.5(a), we provide summaries of the standards we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations. We also provide relevant information about these standards and implementation specifications throughout the preamble.

We have organized the following standards and implementation specifications that we propose to adopt through this rulemaking according to the sections of the Code of Federal Regulation (CFR) in which they would be codified and cross-referenced for associated certification criteria and requirements that we propose to adopt. We note, in certain instances, that we request comment in this proposed rule on multiple standards or implementation specifications that we are considering for adoption *and incorporation by reference* for particular use cases. We include all of these standards and implementation specifications in this section of the preamble.

Content Exchange Standards and Implementation Specifications for Exchanging Electronic Health Information—45 CFR 170.205

- CMS Implementation Guide for Quality Reporting Document Architecture Category I Hospital Quality Reporting Implementation Guide for 2019, May 4, 2018

URL: https://ecqi.healthit.gov/system/files/QRDA_HQR_2019_CMS_IG_final_508.pdf.

This is a direct access link.

Summary: This guide is a CMS Quality Reporting Document Architecture Category I (QRDA I) implementation guide to the *HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture Category I, Release 1, STU Release 5 (published December 2017),* referred to as the HL7 QRDA I STU R5 in this guide. This guide describes additional conformance statements and constraints for EHR data submissions that are required for reporting information to the CMS for the Hospital Inpatient Quality Reporting Program 2019 Reporting Period. The purpose of this guide is to serve as a companion to the base HL7 QRDA I STU R5 for entities such as Eligible Hospitals (EH), Critical Access Hospitals (CAH), and vendors to submit QRDA I data for consumption by CMS systems including for Hospital Quality Reporting (HQR).

- CMS Implementation Guide for Quality Reporting Document Architecture Category III Eligible Clinicians and Eligible Professionals Programs Implementation Guide for 2019, October 8, 2018

URL: https://ecqi.healthit.gov/system/files/2019_CMS_QRDA_III_Eligible_Clinicians_and_EP_IG-508.pdf.

This is a direct access link.

Summary: The Health Level Seven International (HL7) Quality Reporting Document Architecture (QRDA) defines constraints on the HL7 Clinical Document Architecture Release 2 (CDA R2). QRDA is a standard document format for the exchange of electronic clinical quality measure (eCQM) data. QRDA reports contain data extracted from electronic health records (EHRs) and other information technology systems. The reports are used for the exchange of eCQM data between systems for quality measurement and reporting programs. This QRDA guide contains the Centers for Medicare & Medicaid Services (CMS) supplemental implementation guide to the *HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture, Category III, STU Release 2.1 (June, 2017)* for the 2019 performance period. This HL7 base standard is referred to as the HL7 QRDA–III STU R2.1.

- Health Level 7 (HL7®) CDA R2 IG: C–CDA Templates for Clinical Notes R1 Companion Guide, Release 1 (C–CDA 2.1 Companion Guide), March 2017

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=447.

Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Companion Guide to Consolidated Clinical Document Architecture (C–CDA) provides supplemental guidance to the Health Level Seven (HL7) CDA® R2 IG: C–CDA Templates for Clinical Notes STU Release 2.1 in support of the ONC 2015

Edition Health IT Certification Criteria (2015 Edition) Certified Electronic Health Record Technology requirements. This guide provides additional technical clarification and practical guidance to assist implementers to support best practice implementations of the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification.

• Health Level 7(HL7®) CDA R2 Implementation Guide: C–CDA Supplemental Templates for Unique Device Identification (UDI) for Implantable Medical Devices, Release 1–US Realm

URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=486.

Access requires a ''user account'' and a license agreement. There is no monetary cost for a user account and license agreement.

Summary: The Implementation Guide contains guidance, supporting material and new templates to implement support for Unique Device Identifiers (UDIs) for implantable medical devices. The IG identifies changes needed to the C–CDA to better facilitate the exchange of the individual UDI components in the health care system when devices are implanted in a patient. The UDI components include the Device Identifier (DI) and the following individual production identifiers (PI): The lot or batch number, serial number, manufacturing date, expiration date, and distinct identification code.

• National Council for Prescription Drug Programs (NCPDP), Script Standard Implementation Guide, Version 2017071 (Approval Date for ANSI: July 28, 2017)

URL: http://www.ncpdp.org/Standards/Standards-Info.

Access requires registration, membership fee, a user account, and license agreement to obtain a copy of the standard.

Summary: SCRIPT standards are developed for transmitting prescription information electronically between prescribers, pharmacies, payers, and other entities for new prescriptions, changes of prescriptions, prescription refill requests, prescription fill status notifications, cancellation notifications, relaying of medication history, transactions for long-term care, electronic prior authorization and other transactions. New transactions in this update include Prescription drug administration message, New prescription requests, New prescription response denials, Prescription transfer message, Prescription fill indicator change, Prescription recertification, Risk Evaluation and Mitigation Strategy (REMS) initiation request, REMS initiation response, REMS request, and REMS response.

United States Core Data for Interoperability—45 CFR 170.213

• The United States Core Data for Interoperability (USCDI), Version 1 (v1)

URL: https://www.healthit.gov/USCDI.

This is a direct access link.

Summary: The United States Core Data for Interoperability (USCDI) establishes a minimum set of data classes that are required to be interoperable nationwide and is designed to be expanded in an iterative and predictable way over time. Data classes listed in the USCDI are represented in a technically agnostic manner.

Application Programming Interface Standards—45 CFR 170.215

• HL7® FHIR® Foundation, Argonaut Data Query Implementation Guide Server, Version 1.0.2, December 15, 2016

URL: http://www.fhir.org/guides/argonaut/r2/Conformance-server.html.

This is a direct access link.

Summary: This profile defines the expected capabilities of an Argonaut Data Query server when conforming to the Argonaut Data Query IG. The conformance resource includes the complete list of actual profiles, RESTful operations, and search parameters supported by Argonaut Data Query Servers. Servers have the option of choosing from this list to access necessary data based on their local use cases and other contextual requirements.

• HL7® FHIR® Foundation, Argonaut Data Query Implementation Guide, Version 1.0.0, December 23, 2016

URL: http://www.fhir.org/guides/argonaut/r2/.

This is a direct access link.

Summary: The Argonaut Data Query Implementation Guide is based upon the core FHIR DSTU Release 2.0 API and documents security and authorization, data element query of the ONC Common Clinical Data Set, and document query of static documents. This specification describes four use cases and sets search expectations for each. Argonaut uses the SMART Guide for apps that connect to EHR data.

• Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) Release 2.0 Draft Standard for Trial Use (DSTU), Version 1.0.2–7202, October 24, 2015

URL: http://hl7.org/fhir/DSTU2/index.html.

This is a direct access link.

Summary: The Fast Healthcare Interoperability Resources (FHIR) Draft Standard for Trial Use (DSTU) Release 2.0, Version 1.0.2 is designed to enable information exchange to support the provision of health care in a wide variety of settings. The specification builds on and adapts modern, widely used, RESTful practices to enable the provision of integrated health care across a wide range of teams and organizations. HL7 FHIR solutions are built from a set of modular components called ''Resources''. These Resources can easily be assembled into working systems that solve real world clinical and administrative problems at a fraction of the price of existing alternatives. HL7 FHIR is suitable for use in a wide variety of contexts (*e.g.,* mobile phone apps, cloud communications, EHR-based data sharing, and server communication in large institutional health care providers). All resources have the following features in common: A URL that identifies it; common metadata; a human-readable XHTML summary; a set of defined common data elements; and an extensibility framework to support variation in health care.

• Health Level 7 (HL7®) Version 3.0.1 Fast Healthcare Interoperability Resources Specification (FHIR®) Release 3 Standard for Trial Use (STU), April 19, 2017

URL: http://hl7.org/fhir/STU3/index.html.

This is a direct access link.

Summary: The Fast Healthcare Interoperability Resources (FHIR®) Standard for Trial Use (STU) Release 3 leverages the latest web standards and applies a tight focus on implementation. FHIR solutions are built from a set of modular components called ''Resources''. These resources can easily be assembled into working systems that solve real world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR is suitable for use in a wide variety of contexts—mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional health care providers, and much more. This third STU release includes a significant increase in the number of supported resources as well

as revisions to previously published resources reflecting implementer feedback and increased maturity and stability.

• Health Level 7 (HL7®) Version 4.0.0 Fast Healthcare Interoperability Resources Specification (FHIR®) Release 4, December 27, 2018

URL: http://hl7.org/fhir/R4/.

This is a direct access link.

Summary: The Fast Healthcare Interoperability Resources (FHIR®) Release 4 provides the first set of normative FHIR resources. This normative designation means that the future changes will be backward compatible for the first time. These resources define the content and structure of core health data which can be used by developers to build standardized applications. Release 4 provides new standard operation on how to obtain data from multiple patients via FHIR. API services that focus on multiple patients would enable health care providers to manage various internal patient populations as well as external services a health care provider may contract for to support quality improvement, population health management, and cost accountability vis-à-vis the provider's partners (*e.g.,* health plans).

• Health Level 7 (HL7®) Implementation Specification—FHIR Profile: Consent2Share FHIR Consent Profile Design, December 11, 2017

URL: https://gforge.hl7.org/gf/project/cbcc/frs/?action=FrsReleaseView&release_id=1259.

The standard can be accessed through this link.

Summary: The Consent2Share FHIR Consent Profile Design provides instructions for using the FHIR ''Consent'' resource to capture a record of a health care consumer's privacy preferences. Implementing an instance of the FHIR Consent resource based on this guide allows for a patient consent to permit or deny identified recipient(s) or recipient role(s) to perform one or more actions regarding a patient's health information for specific purposes and periods of time.

• API Resource Collection in Health (ARCH) Version 1

URL: https://www.healthit.gov/ARCH.

This is a direct access link.

Summary: The API Resource Collection in Health (ARCH) is an implementation specification that list a set of base FHIR resources that Health IT Modules would need to support. The ARCH aligns with, and is directed by, the data policy specified in the US Core Data for Interoperability (USCDI) standard.

• SMART Application Launch Framework Implementation Guide Release 1.0.0, November 13, 2018

URL: http://hl7.org/fhir/smart-app-launch/.

This is a direct access link.

Summary: SMART on FHIR provides reliable, secure authorization for a variety of app architectures through the use of the OAuth 2.0 standard. This Authorization Guide supports the four uses cases defined for Phase 1 of the Argonaut Project. This profile is intended to be used by developers of apps that need to access FHIR resources by requesting access tokens from OAuth 2.0 compliant authorization servers. The profile defines a method through which an app requests authorization to access a FHIR resource, and then uses that authorization to retrieve the resource. Other Health Insurance Portability and Accountability Act (HIPAA)-mandated security mechanisms, such as end-user authentication, session time-out, security auditing, and accounting of disclosures, are outside the scope of this profile.

• IETF OAuth 2.0 Dynamic Client Registration Protocol (RFC 7591), July 2015

URL: https://tools.ietf.org/html/rfc7591.

This is a direct access link.

Summary: This specification defines mechanisms for dynamically registering OAuth 2.0 clients with authorization servers. Registration requests send a set of desired client metadata values to the authorization server. The resulting registration responses return a client identifier to use at the authorization server and the client metadata values registered for the client. The client can then use this registration information to communicate with the authorization server using the OAuth 2.1 protocol. This specification also defines a set of common client metadata fields and values for clients to use during registration.

• OpenID Connect Core 1.0 Incorporating Errata Set 1, November 8, 2014

URL: http://openid.net/specs/openid-connect-core-1_0.html.

This is a direct access link.

Summary: OpenID Connect 1.0 is a simple identity layer on top of the OAuth 2.0 protocol. It enables Clients to verify the identity of the End-User based on the authentication performed by an Authorization Server, as well as to obtain basic profile information about the End-User in an interoperable and REST-like manner. This specification defines the core OpenID Connect functionality: Authentication built on top of OAuth 2.0 and the use of Claims to communicate information about the End-User. It also describes the security and privacy considerations for using OpenID Connect.

XII. Response to Comments

Because of the large number of public comments normally received in response to **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

We note that, throughout this proposed rule, we identified areas where we need more information before making a proposal (*i.e.,* requests for information). We note that comments we receive in response to these requests for information will not necessarily be addressed in the final rule, but will be used to inform future rulemaking.

XIII. Collection of Information Requirements

The Paperwork Reduction Act of 1995 (PRA) requires agencies to provide a 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to the Office of Management and Budget for review and approval. In order to fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section. To comment on the collection

of information or to obtain copies of the supporting statements and any related forms for the proposed paperwork collections referenced in this section, email your comment or request, including your address and phone number to *Sherrette.funn@hhs.gov,* or call the Reports Clearance Office at (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60 days.

A. ONC–ACBs

We propose to add new ONC–ACB collection and reporting requirements for the certification of health IT to the 2015 Edition (and any subsequent edition certification) in § 170.523(p), (q), (t), and § 170.550(1).

As proposed for §§ 170.550(l), ONC–ACBs would not be able to certify health IT until they review and verify health IT developers' attestations confirming that the developers are compliant with Conditions and Maintenance of Certification requirements. ONC–ACBs would also submit the health IT developer attestations to ONC as proposed by § 170.523(q). We believe this will require minimal effort on behalf of ONC–ACBs as the ONC submission part will be electronically facilitated via the CHPL.

As proposed for § 170.523(p)(3), ONC–ACBs would be required to collect and report certain information to ONC related to real world testing plans and results. ONC–ACBs would be required to verify that the health IT developer submits an annual, publicly available real world testing plan and perform a completeness check for both real world testing plans and results. We believe ONC–ACBs will face minimum burden in complying with these new proposed requirements.

As proposed for § 170.523(t), ONC–ACBs would ensure health IT developers opting to take advantage of the Standard Version Advancement Process flexibility per § 170.405(b)(5) provide timely advance written notice to the ONC–ACB and all affected customers. ONC–ACBs would maintain a record of the date of issuance and the content of developers' notices, and timely post content of each notice received publicly on the CHPL attributed to the certified Health IT Module(s) to which it applies. We believe this will require minimal effort on behalf of ONC–ACBs as the submission part will be electronically facilitated via the CHPL.

In the 2015 Edition proposed rule (80 FR 16894), we estimated fewer than ten annual respondents for all of the regulatory ''collection of information'' requirements that applied to the ONC–AA and ONC–ACBs, including those previously approved by OMB. In the 2015 Edition final rule (80 FR 62733), we concluded that the regulatory ''collection of information'' requirements for the ONC–AA and the ONC–ACBs were not subject to the PRA under 5 CFR 1320.3(c). We continue to estimate less than ten annual respondents for all of the proposed regulatory ''collection of information'' requirements for ONC–ACBs under Part 170 of Title 45, including those previously approved by OMB and proposed in this proposed rule. Accordingly, the regulatory ''collection of information'' requirements under the Program described in this section are not subject to the PRA under 5 CFR 1320.3(c). We welcome comments on these conclusions and the supporting rationale on which they are based. For costs estimates of these proposed new regulatory requirements, we refer readers to section XIV. (*Regulatory Impact Analysis*) of this proposed rule.

B. Health IT Developers

We propose in 45 CFR 170.580(a)(2)(iii) that ONC may take action against a health IT developer for failure to comply with Conditions and Maintenance of Certification requirements. We proposed to generally use the same processes previously codified in regulation (§§ 170.580 and 170.581) to take administrative enforcement action. These processes would require health IT developers to submit information to ONC to facilitate and conclude its review. The PRA, however, exempts these information collections. Specifically, 44 U.S.C. 3518(c)(1)(B)(ii) excludes collection activities during the conduct of administrative actions or investigations involving the agency against specific individuals or entities.

We propose in 45 CFR 170.402(b)(1) that a health IT developer must, for a period of 10 years beginning from the date each of a developer's health IT is first certified under the ONC Health IT Certification Program, retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program. We believe it will take approximately two hours per week on average to comply with our proposed record retention requirement. We welcome comments if stakeholders believe more or less time should be included in our estimate.

TABLE 4—ESTIMATED ANNUALIZED TOTAL BURDEN HOURS FOR HEALTH IT DEVELOPERS TO COMPLY WITH RECORDS RETENTION REQUIREMENTS

Code of Federal regulations section	Number of health IT developers	Average burden hours	Total
45 CFR 170.402(b)(1)	458	104	47,632
Total Burden Hours			47,632

XIV. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to meet our statutory responsibilities under the 21st Century Cures Act (Cures Act) and to advance HHS policy goals to promote interoperability and mitigate burden for stakeholders. Proposals that could result in monetary costs for stakeholders include the: (1) Proposals to update the 2015 Edition health IT certification criteria; (2) proposals related to Conditions and Maintenance of Certification for a health IT developer; (3) proposals related to oversight for the Conditions and Maintenance of Certification; and (4) proposals related to information blocking.

While much of the costs of this proposed rule will fall on health IT developers that seek to certify health IT under the ONC Health IT Certification Program (Program), we believe the implementation and use of health IT certified to the 2015 Edition (including the new criteria in this proposed rule), compliance with the Conditions and Maintenance of Certification, and the

limited exceptions to information blocking proposed would ultimately result in significant benefits for health care providers and patients. We outline some of these benefits below. We emphasize in this regulatory impact analysis (RIA) that we believe this proposed rule would create opportunities for new market entrants and would remove barriers to interoperability and electronic health information exchange, which would greatly benefit health care providers and patients.

We note in this RIA that there were instances in which we had difficulty quantifying certain benefits due to a lack of applicable studies and/or data. However, in such instances, we highlight the significant qualitative benefits of our proposals to advance an interoperable health system that empowers individuals to use their electronic health information (EHI) to the fullest extent and enables health care providers and communities to deliver smarter, safer, and more efficient care.

B. Alternatives Considered

We assessed whether there are alternatives to our proposals, specifically our proposals concerning EHI export, application programming interfaces (APIs), and real world testing. We have been unable to identify alternatives that would appropriately implement our responsibilities under the Cures Act and support interoperability. We believe our proposals take the necessary steps to fulfill the mandates specified in the Public Health Service Act (PHSA), as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act and the Cures Act, in the least burdensome way. We are, however, open to less burdensome alternatives that meet statutory requirements and our goals. Accordingly, we welcome comments on our assessment and any alternatives we should consider.

C. Overall Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs, the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), and Executive Order 13132 on Federalism (August 4, 1999).

1. Executive Orders 12866 and 13563—Regulatory Planning and Review Analysis

Executive Orders 12866 on Regulatory Planning and Review and 13563 on Improving Regulation and Regulatory Review direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). OMB has determined that this proposed rule is an economically significant rule as the potential costs associated with this proposed rule could be greater than $100 million per year. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of this proposed rule.

2. Executive Order 13771—Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs was issued on January 30, 2017 and directs agencies to repeal two existing regulations for each new regulation issued in fiscal year (FY) 2017 and thereafter. It further directs agencies, via guidance issued by the Office of Management and Budget (OMB), that the total incremental costs of all regulations should be no greater than zero in FY 2018. The analysis required by Executive Order 13771, as supplemented by Executive Order 13777, adds additional requirements for analysis of regulatory actions. The new requirements under Executive Orders 13771 and 13777 do not change or reduce existing requirements under Executive Orders 12866 or 13563.

a. Costs and Benefits

We have estimated the potential monetary costs and benefits of this proposed rule for health IT developers, health care providers, patients, ONC-Authorized Certification Bodies (ONC–ACBs), ONC-Authorized Testing Laboratories (ONC–ATLs), and the federal government (*i.e.,* ONC), and have broken those costs and benefits out into the following categories: (1) Deregulatory actions (no associated costs); (2) updates the 2015 Edition Health IT certification criteria; (3) Conditions and Maintenance of Certification for a health IT developer; (4) oversight for the Conditions and Maintenance of Certification; and (5) information blocking.

In accordance with Executive Order 12866, we have included the RIA summary table as Table 25. In addition, we have included a summary to meet the regulatory reform analysis requirements under Executive Order 13771.

We note that we have rounded all estimates to the nearest dollar and that all estimates are expressed in 2016 dollars as it is the most recent data available to address all cost and benefit estimates consistently. We also note that estimates presented in the following ''Employee Assumptions and Hourly Wage,'' ''Quantifying the Estimated Number of Health IT Developers and Products,'' and ''Number of End Users that Might Be Impacted by ONC's Proposed Regulations'' sections are used throughout this RIA.

For proposals where research supported direct estimates of impact, we estimated the benefits. For proposals where no such research was identified to be available, we developed estimates based on a reasonable proxy.

We note that interoperability can positively impact patient safety, care coordination, and improve health care processes and health outcomes.[144] However, achieving interoperability is a function of a number of factors including the capability of the technology used by health care providers. Therefore, to assess the benefits of our proposals, we must first consider how to assess their respective effects on interoperability holding other factors constant.

For the purpose of this analysis, we used regression analysis to calculate the impact of our real world testing and API proposals on interoperability. We assumed that the real world testing and API proposals would collectively have the same impact on interoperability as health IT certified to the 2014 Edition. Therefore, we estimated linear probability models that identified the impact of 2014 Edition certified health IT on hospitals' interoperability.[145] We used data from the 2014 and 2015 American Hospital Association (AHA) Annual Survey Information Technology Supplement (IT Supplement), which consists of an analytic sample of 4,866 observations of non-federal acute care

[144] *https://www.qualityforum.org/Publications/2017/09/Interoperability_2016-2017_Final_Report.aspx.*

[145] The interoperability dependent variable is a binary indicator for whether a hospital routinely sends, receives, and integrates summary of care records electronically outside of its system and finds any health information electronically outside of its system.

hospitals that responded to the IT Supplement.[146] We controlled for additional factors such as participation in a health information exchange organization, hospital characteristics, and urban/rural status. More specifically, we used the following explanatory variables:

Edition = 1 if a hospital adopted 2014 Edition EHR, 0 otherwise
RHIO = 1 if a hospital participates in health information exchange organization, 0 otherwise
Government = 1 if a hospital is publically owned, 0 otherwise
Alt_teaching = 1 if a hospital is teaching, 0 otherwise
Nonprofit = 1 if a hospital is not for profit, 0 otherwise
Largebed = 1 if a hospital has more than 399 beds, 0 otherwise
Medbed = 1 if a hospital's number of beds is between 100 and 399, 0 otherwise
Urban_rural = 1 if a hospital is urban, 0 otherwise
CAH = 1 if a hospital is critical access, 0 otherwise
Year = year of the data (2014 and 2015)
S = state fixed effects

We found a statistically significant marginal effect of using 2014 Edition certified health IT associated with a five percentage point increase in interoperability.[147]

While we acknowledge that there might be shared benefits across proposals, we have taken steps to ensure that the benefits attributed to each proposal is unique to the proposal referenced. We assumed that this marginal effect is true for our proposals and distributed the 5% benefit across our real world testing and API proposals at (.1–1%) to (1–4%) respectively. Moreover, the number of providers impacted is proposal specific. Given data limitations, we believe this approach allows us to estimate the benefits of our proposals without double counting the impact each proposal might have on interoperability.

Employee Assumptions and Hourly Wage

We have made employee assumptions about the level of expertise needed to complete the proposed requirements in this section. For wage calculations for federal employees and ONC–ACBs, we have correlated the employee's expertise with the corresponding grade and step of an employee classified under the General Schedule (GS) Federal Salary Classification, relying on the associated employee hourly rates for the Washington, DC locality pay area as published by the Office of Personnel Management for 2016.[148] We have assumed that overhead costs (including benefits) are equal to 100% of pre-tax wages. Therefore, we have doubled the employee's hourly wage to account for overhead costs. We have concluded that a 100% expenditure on benefits is an appropriate estimate based on research conducted by HHS.[149]

We have used Bureau of Labor Statistics (BLS) data to calculate private sector employee wage estimates (*e.g.,* health IT developers, health care providers, HINs, attorneys, etc.), as we believe BLS provides the most accurate and comprehensive wage data for private sector positions. Just as with the General Schedule Federal Salary Classification calculations, we have assumed that overhead costs (including benefits) are equal to 100% of pre-tax wages.

All wage estimates (GS and BLS) have been calculated in 2016 dollars because OMB requested that agencies generate cost and benefit estimates in 2016 dollars under Executive Order 13771. If we were to represent wage estimates in 2017 dollars, then costs and benefits, including net benefits, would increase by 4%. For our final rule, we will consider using 2017 and even 2018 dollars, if available, for our cost and benefit estimates.

We welcome comments on our methodology for estimating labor costs.

Quantifying the Estimated Number of Health IT Developers and Products

In this section, we describe the methodology used to assess the potential impact of new 2015 Edition certification criteria on the availability of certified products in the health IT market. This analysis is based on the number of certified health IT products (*i.e.,* Health IT Modules), product capability, and the number of health IT developers that left, merged, and/or entered the health IT market between the establishment of the Program and implementation of the 2011 Edition and the implementation of the 2014 Edition.[150]

Market consolidation may occur as a result of a natural evolvement of a new industry.[151] We account for this factor in our analysis. In Table 5 below, we quantify the extent to which the certified health IT market consolidated between the 2011 Edition and 2014 Edition. We found that the number of health IT developers certifying products between the 2011 Edition and 2014 Edition decreased by 22.1% and the number of products available decreased by 23.2%.

TABLE 5—CERTIFIED HEALTH IT MARKET CONSOLIDATION FROM THE 2011 EDITION TO THE 2014 EDITION [a]

	2011 Edition	2014 Edition	Market consolidation (%)
Health IT Developers	1,017	792	−22.1
Products	1,408	1,081	−23.2

[a] For the purposes of these market consolidation calculations, we included the total number of active or suspended health IT products and their developers. Withdrawn products and their developers were excluded from this total.

Not all products are certified to all of the edition's certification criteria available in the Program. Modular certification allows a health IT developer to present a product for certification to a narrower scope of

[146] American Hospital Association Health IT Supplement Survey, *http://www.ahadata.com/aha-healthcare-database/.*

[147] Results were similar when we used logit or Probit specifications.

[148] *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB_h.pdf.*

[149] *See* U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE), *Guidelines for Regulatory Impact Analysis,* at 28–30 (2016), *available at https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf.*

[150] Availability of 2014 CEHRT for Meaningful Users Providers, Health IT Policy Committee Data Update (Sept. 9, 2015), *available at http://www.healthit.gov/FACAS/sites/faca/files/HITPC_Data_Update_Presentation_Final_2015-09-09.pdf.*

[151] *See* Graeme K. Deans, Fritz Kroeger, and Stefan Zeisel, The Consolidation Curve (Dec. 2002); J. David Cummins and Maria Rubio-Misas, *Deregulation, Consolidation, and Efficiency: Evidence from the Spanish Insurance Industry,* Journal of Money, Credit and Banking, Vol. 38, No. 2 (Mar. 2006), at 323–55; Martin Gaynor and Deborah Haas-Wilson, *Change, Consolidation, and Competition in Health Care Markets,* The Journal of Economic Perspectives, Vol. 13, No. 1 (Winter 1999), at 141–64.

specific use cases, which may be impacted at differing levels or may not be impacted by the proposals in this proposed rule. Therefore, we have estimated the number of 2015 Edition certified health IT products and health IT developers impacted by each proposal using proxies from historical data. Using the rates identified in Table 5, we then applied our estimate for market consolidation to estimate the number 2015 Edition certified health IT products and health IT developers that would be impacted by our policies in this proposed rule. Specifically, to estimate the number of 2015 Edition products and health IT developers in the market, we have assumed:

1. *Products capable of recording EHI will include new certification criteria.* We assume that products capable of recording patient health data will be the types of products most likely to be impacted by and include the new proposed certification criteria.

2. *Products capable of recording EHI data available in 2015 equal the number of products available in 2014.* In 2014, there were 710 products by 588 developers capable of recording EHI. Since the new criteria involve the access to and movement and exchange of EHI, we used only products that record EHI as a basis for our estimates. We believe the 2014 totals reflect a realistic estimate of the currently available products and their developers that could include the new 2015 certification criteria.

3. *Market consolidation rates denoted in Table 5 hold constant.* We assume that the rate of market consolidation for products (−23.2%) and health IT developers (−22.1%) from the 2011 Edition to the 2014 Edition holds constant for the 2015 Edition.

As shown in Table 6 below, based on the assumptions 1–3 above, we have estimated the total number of 2015 products (545) and their developers (458).

TABLE 6—TOTAL NUMBER OF HEALTH IT DEVELOPERS AND PRODUCTS BY SCENARIO

Scenario	Number of health IT developers	Number of products
2015 Edition Projection—All Products	617	830
2015 Edition Projection—Products Capable of Recording EHI	458	545

Number of End Users That Might Be Impacted by ONC's Proposed Regulations

For the purpose of this analysis, the population of end users differs according to the regulatory action proposed. In many cases, the end user population impacted is the number of hospitals and health care providers that possess certified health IT. Due to data limitations, our analysis regarding the number of hospitals and health care providers impacted by the regulatory action is based on the number of hospitals and health care providers that have historically participated in the Centers for Medicare & Medicaid Services (CMS) EHR Incentive Programs. Although there are limitations to this approach, participants in the CMS EHR Incentive Programs represent an adequate sample on which to base our estimates.[152] We estimate 439,187 health care providers[153] in 95,470 clinical practices[154] and 4,519 hospitals[155] will be impacted.

(1) Deregulatory Actions

Costs

We do not expect costs to be associated with the deregulatory action proposals.

Benefits

We expect the proposals for deregulatory actions to result in significant benefits for health IT developers, providers, ONC–ACBs, ONC–ATLs, and ONC. These expected benefits are detailed below.

1.1 Removal of the Randomized Surveillance Minimum Threshold Requirements

We have proposed to revise § 170.556(c) by revising the requirement that ONC–ACBs *must* conduct in-the-field, randomized surveillance and in its place specify that ONC–ACBs *may* conduct in-the-field, randomized surveillance. We have further proposed to remove § 170.556(c)(2), which specifies that ONC–ACBs must conduct randomized surveillance for a minimum of 2% of certified health IT products per year. We have also proposed to remove the requirement that ONC–ACBs make a good faith effort to complete randomized surveillance and the circumstances permitted for exclusion from this requirement found in § 170.556(c)(5).

These proposals would reduce burden on health care providers by reducing their exposure to randomized in-the-field surveillance of their health IT products. Health care providers expressed concern about the time commitment to support ONC–ACB randomized surveillance of health IT products, particularly if no non-conformities with certified health IT were found. Providers have generally stated that reactive surveillance (*e.g.,* complaint-based surveillance) is a more logical and economical approach to surveillance of health IT products implemented in a health care setting. The proposal in this proposed rule would provide health IT developers more time to focus on interoperability. It would also provide ONC–ACBs more time to respond to reactive surveillance, including health care provider complaints about certified health IT. In the 2015 Edition final rule, we did not independently estimate the costs for randomized surveillance. Rather, we relied on prior regulatory cost estimates for all surveillance actions. One of our ONC–ACBs charges a $3,000 annual fee per product for surveillance due to the new randomized surveillance requirements and to help normalize their revenue stream during down cycles between certification editions. Using this fee as a cost basis and

[152] *See* Office of the National Coordinator for Health Information Technology, *Office-based Health Care Professionals Participating in the CMS EHR Incentive Programs* (Aug. 2017), *dashboard.healthit.gov/quickstats/pages/FIG-Health-Care-Professionals-EHR-Incentive-Programs.php;* Office of the National Coordinator for Health Information Technology, *Hospitals Participating in the CMS EHR Incentive Programs* (Aug. 2017), *dashboard.healthit.gov/quickstats/pages/FIG-Hospitals-EHR-Incentive-Programs.php.*

[153] This estimate is the total number of eligible providers that ever participated in the CMS Medicare and Medicaid Electronic Health Record Incentive Program.

[154] This number was estimated based on the de-duplicated number of practices that had at least one clinician participate in the CMS Medicare Electronic Health Record Incentive Program.

[155] This estimate is the total number of eligible hospitals that ever participated in the CMS Medicare Electronic Health Record Incentive Program.

assuming it would apply to all certified health IT (as opposed to the market-adjusted universe of health IT that is used in other calculations in this RIA), we estimate that our proposal to remove the randomized surveillance ''2% minimum threshold'' requirements would result in cost savings between $6.8 and $13.7 million for all stakeholders. To arrive at this estimate, we multiplied the $3,000 annual fee per product for surveillance by the total number of products certified to the 2014 Edition which was 4,559 products at the time ($3,000 * 4,559 = $13.7 million). We anticipate the number of products certified for 2014 to decrease to a little as half of the original count over time. Therefore, we estimated the low end to be half of the $13.7 million (.5 * $13.7 million = $6.8 million). This estimate is based on feedback we received from our ONC–ATL and ONC–ACB stakeholders. ONC–ACBs performed randomized surveillance an average of 22 times the first year the requirement was in effect. The following year surveillance was performed an average of 2 times. We cannot predict how many randomized surveillance events the ONC–ACBs will perform now that we are not enforcing the requirement. It will be completely at the discretion of the ONC–ACBs.

We note that we considered other potential benefits that we were unable to quantify. We considered that health care provider burden may decrease from the elimination of the 2% minimum threshold requirements because a provider would previously aid the ONC–ACB in software demonstrations. However, we acknowledge that in the long term and moving forward, providers will likely be the party reporting more of the complaints that could result in reactive surveillance. We also considered that an additional benefit of the proposal would be reduced burden on ONC–ACBs. Feedback from ONC–ACBs indicates that having to meet a set number of surveillance activities in 12 months can be quite burdensome, especially when factoring in the active engagement necessary from provider participants. Last, we considered the potential benefit to health IT developers in having more surveillance focused on situations dealing with actual end-user concerns and/or difficulties. Health IT developers have indicated that they benefit from such surveillance, as feedback about conformance and capability can improve their products.

We welcome comments on potential means, methods, and relevant comparative studies and data that we could use to better quantify these benefits.

1.2 Removal of the 2014 Edition From the Code of Federal Regulations

We have proposed to remove the 2014 Edition certification criteria from the Code of Federal Regulations, which would directly benefit health IT developers, ONC–ACBs, ONC–ATLs, and ONC and indirectly benefit health care providers. When looking at the cost savings for removing the 2014 Edition certification criteria, we considered the current costs for maintaining those certifications and their surveillance (reactive), as well as the maintenance and administrative costs associated with supporting customer use of certified health IT for CMS EHR Incentive Program participation. The estimates below consider ONC analysis of the financial sustainability of ONC–ACBs and reflect data from as late as 2015.

We estimate that health IT developers would realize monetary savings from no longer supporting the 2014 Edition certification criteria due to a reduction in activities related to maintaining certification and surveillance. We are aware that one of our ONC–ACBs charges an inherited certified status (ICS) fee of $1,000. This fee has been applied over the last calendar year. Over that time period, the number of new, unique 2014 Edition products has been declining (24 products in the last calendar year, and no new products in the last four months) compared to the number of ICS certifications (569). Just assuming the cost of continued ICS certification, health IT developers would be paying approximately $569,000 each year to keep their 2014 Edition products up-to-date.

We are not aware of comparable fees charged by ONC–ATLs; however, based on our experience with the Program, we expect health IT developers would realize similar cost savings associated with ONC–ATL maintenance of the testing component associated with ICS. Thus, we estimate an additional $569,000 cost savings for health IT developers due to the reduced testing requirements.

A recent study conducted by ONC indicates that 2014 Edition ICS certification is not profitable for ONC–ACBs, which is why one ONC–ACB charged an additional $3,000 annual fee per product for surveillance for 2015 Edition certifications. In 2015, the net income for ONC–ACBs dropped 99% from about $5,310,000 in 2014 to $67,000 due to a decline in revenue from a drop in new 2014 Edition certified health IT products without a significant drop in expenses. We do not have enough information to calculate what percentage of ONC–ACB expenses are the direct result of 2014 Edition certification maintenance; however, our research indicates that it is significantly less profitable for ONC–ACBs to maintain 2014 Edition certification criteria (*e.g.,* through ICS attestation and reactive surveillance) than to certify new 2014 Edition certified health IT products.

We also attempted to identify a potential reduction in maintenance and administrative costs as a result of removing 2014 Edition certification criteria. We could not obtain data to conduct a full quantitative analysis specific to the reduction of health IT developer and health care provider costs related to supporting and maintaining the 2014 Edition. We seek comment on methods to quantify potential costs for maintaining and supporting products to previous editions.

We did conduct a review of academic literature and qualitative analysis regarding potential savings from no longer supporting the 2014 Edition. We looked at data in IT industry systems as whole, which showed that upgrading outdated legacy systems saves resources otherwise spent on maintaining compatibilities to multiple systems and also increases quality and efficiency.[156] Furthermore, as technology evolves, newer software and products allow for smoother updates compared to their predecessors. Newer products provide better security features that are able to address both new and existing issues. In addition, older software has an increased risk of failure, which, in the health IT industry, increases risk to patient safety.

From the implementer's perspective, the research indicates that retaining legacy systems tends to inhibit scalability and growth for businesses. The perpetuity of outdated legacy systems increases connection and system integration costs and limits the ability to realize increased efficiency through IT implementation. Newer products are developed to current specifications and updated standards, which decreases barriers and marginal cost of ancillary product implementation and increases the accessibility of data in ancillary systems—including via mobile devices and the latest applications. Finally, office staff in a health care setting would no longer need to be trained to accommodate differing data access

[156] James Crotty and Ivan Horrocks, *Managing legacy system costs: A case study of a meta-assessment model to identify solutions in a large financial services company,* Applied Computing and Informatics (2017), at 1–9.

needs or workarounds required to integrate to the legacy product.[157]

The research also indicates that retaining legacy software would not be beneficial or profitable to the health IT market. Prolonging backwards compatibility of newer products to legacy systems encourages market fragmentation.[158] Limiting fragmentation encourages innovation and attracts more developers by reducing barriers and the marginal cost of development to multiple platforms. Health IT stakeholders have expressed that system fragmentation increases the cost to develop and maintain health IT connectivity for data exchange and to integrate software supporting administrative and clinical processes, as well as limiting the feasibility of developing products to support specialty clinical care. This direct feedback suggests that fragmentation is having a negative impact on the interoperability and usability of health IT systems for health care providers. We intend to encourage the health IT market to keep progressing with a baseline expectation of functionalities that evolve over time. This requires limiting fragmentation by no longer supporting outdated or obsolete legacy software.[159]

We also estimate that additional savings could be realized by reducing regulatory complexity and burden caused by having two certification editions. For example, in the 2015 Edition final rule, we added new requirements, such as disclosure and transparency requirements, that applied to all certified product editions. This required significant effort by health IT developers and ONC–ACBs to execute the requirements, and both groups found it challenging to complete the task in the original timeframe provided by ONC. We have observed that the task of managing two different editions within different rules increases complexity and burden for ONC staff, contractors, ONC–ACBs, CMS programs referencing the certification criteria, and other stakeholders, as compared to our proposal to remove the 2014 Edition certification criteria. However, we are unable to estimate these benefits because we have no means for quantifying the benefits gained from only using the 2015 Edition. We welcome comments on potential means, methods, and relevant comparative studies and data that we could use to quantify these benefits.

We also expect that health care providers would benefit from this proposal because such action would likely motivate health IT developers to certify health IT products to the 2015 Edition, thus enabling providers to use the most up-to-date and supported systems to care for patients. The 2015 Edition certification criteria facilitates greater interoperability for several clinical health information purposes and enables health information exchange, including APIs, through new and enhanced certification criteria, standards, and implementation specifications. The certification criteria also allow for updates to documents and data standards and focus on the establishment of an interoperable health information infrastructure. We welcome comments on potential means, methods, and relevant comparative studies and data that we could use to quantify these benefits.

1.3 Removal of the ONC-Approved Accreditor From the ONC Health IT Certification Program

We expect ONC to realize monetary cost savings from the proposal to remove the ONC- Approved Accreditor (ONC–AA) from the Program. We expect ONC to realize costs savings from no longer: (1) Developing and publishing a **Federal Register** Notice and listserv; (2) monitoring the open application period and reviewing and making decisions regarding applications; and (3) oversight and enforcement of the ONC–AA. We have calculated the estimated annual cost savings for this proposal, taking into consideration that the ONC–AA renewed its status every three years.

The ONC–AA's expertise is in the ISO/IEC 17065 standard. Therefore, to effectively collaborate with the ONC–AA for Program activities, ONC allocates resources for working with the ONC–AA and informing the ONC–AA of scheme requirements and applicable policy interpretations, which we have and can provide directly to the ONC–ACBs. The amount of ONC resources allocated depends on current Program activities and need. For our calculations, we used the estimated hours for collaborating with and informing an ONC–AA in 2017 (using 2016 wage estimates). We estimate that ONC spent approximately 110 hours collaborating with the ONC–AA in 2017, which includes (all at the GS–13, Step 1 level): Annual assessments; providing appropriate guidance; implementing new requirements and initiatives; and consultations as necessary. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. Therefore, we estimate the annual cost savings to be $3,238.

We estimate that ONC would commit approximately eight hours of staff time to develop the **Federal Register** Notice, which would include approximately: Four hours for drafting and review by an analyst at the GS–13, Step 1 level; two hours for review and analysis by senior certification staff at the GS–14, Step 1 level; and two hours for review and submittal for publication by Immediate Office staff at the GS–15, Step 1 level. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. The hourly wage with benefits for a GS–14, Step 1 employee located in Washington, DC is approximately $104.34. The hourly wage with benefits for a GS–15, Step 1 employee located in Washington, DC is approximately $122.74. Therefore, we estimate the annual cost savings to be $269. Additionally, we estimate a cost of $477 to publish each page in the **Federal Register**, which includes operational costs. The **Federal Register** Notice for ONC–AAs requires, on average, one page in the **Federal Register** (every three years), so we estimate an additional annual cost savings of $159.

We estimate that ONC would commit approximately two hours of staff time by an analyst at the GS–13, Step 1 level to draft, review, and publish the listserv to announce the **Federal Register** Notice. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. Therefore, we estimate the annual cost savings to be $59.

We estimate that ONC would commit approximately 25 hours of staff time to manage the open application process, review applications and reach application decisions, which would include approximately: 20 hours by an analyst at the GS–13, Step 1 level; three hours by senior certification staff at the GS–14, Step 1 level; and two hours for review and approval by Immediate Office staff at the GS–15, Step 1 level. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. The hourly wage with benefits for a GS–14, Step 1 employee located in Washington, DC is approximately $104.34. The hourly wage with benefits for a GS–15, Step 1 employee located in Washington, DC is approximately $122.74. Therefore, we estimate the annual cost savings to be $775.

Taking all of these potential costs savings into consideration, we estimate

[157] *Id.*

[158] Il-Horn Hann, Byungwan Koh, and Marius F. Niculescu, *The Double-Edged Sword of Backward Compatibility: The Adoption of Multigenerational Platforms in the Presence of Intergenerational Services,* Inform. Systems Res. (2016), at 112–30.

[159] *Id.*

the overall annual costs savings for our proposal to remove the ONC–AA from the Program to be $4,500.

1.4 Removal of Certain 2015 Edition Certification Criteria

In section III.B.4 of this proposed rule, we propose to remove the following certification criteria from the 2015 Edition: § 170.315(b)(4) ''Common Clinical Data Set summary—create;'' (b)(5) ''Common Clinical Data Set summary—receive'', § 170.315(a)(10) ''Drug formulary and preferred drug list checks,'' § 170.315(a)(11) ''Smoking status,''§ 170.315(a)(13) ''Patient-specific education resources'' and § 170.315(e)(2) ''Secure messaging.''

For determining calculations for the majority of the proposed removal of certain 2015 Edition certification criteria, we used the assumptions below. For the proposed removal of § 170.315(b)(4) Common Clinical Data Set summary—create and (b)(5) Common Clinical Data Set summary—receive, we took a slightly different approach discussed in section 1.4.1.

In the 2015 Edition final rule, we estimated the costs for developing and preparing health IT to meet the 2015 Edition certification criteria. The development and preparation costs we estimated were derived through a health IT developer per criterion cost. We estimated the development and preparation costs over a four-year period and we projected the costs would be unevenly distributed. In figuring out the cost savings for the deregulatory actions, we initially used the distribution from the 2015 Edition, but then adjusted the percentages of development and preparation costs due to current empirical and anecdotal evidence. The distribution was reevaluated to account for 2019 and we estimate the actual development and preparation distribution for 2018 to be 35% and for 2019 to be 15%. We took the average development and preparation cost estimates (low and high) per criterion from Table 14 of the 2015 Edition final rule (80 FR 62737). We then used our new distribution to figure out the cost per year for years 2018 and 2019. We took the total estimated costs for 2018 and 2019 and divided that by 12 to determine the cost savings per month and took a range of 6–12 months.

To determine the testing costs of the deregulatory actions, we took the number of health IT developers who develop products for certification for the identified criteria from the 2015 Edition final rule and then figured out the average cost per criterion. Based on the costs that one of the ONC–ATLs charges for testing, we estimated the average cost for testing per criterion and determined subsequent cost savings. In 2017, only about five to ten percent of products have been tested and certified compared to the number of certified 2014 Edition products. Therefore, up to 90 to 95 percent of products remain to be tested and certified to the 2015 Edition.

We estimate the total cost savings by multiplying the number of health IT developers who developed products for certification to a certain criterion by the estimated cost per criterion, $475. We then took five percent of that number to figure out the high end for the cost savings. We then took 10 percent to figure out the low end. The five percent was derived from looking at the number of unique developers who have at least one active 2014 Edition product and the number of unique developers who have at least one active 2015 Edition. The denominator is the number of unique developers who have at least one active 2014 Edition product, which is 793. The numerator is the number of unique developers who have at least one active 2015 Edition product and one active 2014 edition product, which is 41. (41/793 = 0.0517024 or 5 percent).

1.4.1 Common Clinical Data Set Summary Record Criteria

We propose to remove the Common Clinical Data Set summary—create (§ 170.315(b)(4)) and Common Clinical Data Set summary—receive (§ 170.315(b)(5)) criteria.

We expect ONC to realize cost savings associated with internal infrastructure support and maintenance, which would include actions such as (1) developing and maintaining information regarding these criteria on the ONC website; (2) creating documents related to these criteria and making those documents 508 compliant; (3) updating, revising, and supporting Certification Companion Guides, test procedures, and test tools; and (4) responding to inquiries concerning these criteria. Based on ONC data on the number of inquiries received since early 2016, we estimate approximately 12 annual inquiries about § 170.315(b)(4) and (5) respectively (24 total inquiries for two criteria). We estimate it will take an analyst at the GS–13, Step 1 level an average of two hours to conduct all tasks associated with each inquiry. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. Therefore, we estimate the annual cost savings to be $4,238.

We do not expect cost savings associated with software maintenance because both of these criteria incorporate the Common Clinical Data Set and essentially the same data input and validation requirements as the transitions of care criterion (§ 170.315(b)(1)). The removal of these two criteria would not affect the test data and software maintenance costs, as the same test data and software validation elements remain in § 170.315(b)(1) and the Common Clinical Data Set used in other criteria.

ONC–ACBs could realize minimal savings, as they would need to conduct slightly less surveillance based on the two products that are currently certified to these criteria. We expect these potential cost savings to be de minimis and have therefore not estimated them.

Taking all these potential costs savings into consideration, we estimate the overall annual costs savings for our proposal to remove the Common Clinical Data Set summary record certification criteria from the 2015 Edition to be $4,238. We welcome comments on the above estimates and methods we could use to better quantify these benefits.

1.4.2 Drug Formulary and Preferred Drug List Checks

We propose to remove the 2015 Edition ''drug formulary and preferred drug list checks'' criterion in § 170.315(a)(10)). To calculate the cost savings for removing this criterion, we used the 2015 Edition estimated costs for development and preparation for this criterion which were between $15,750 and $31,500. We believe that 35% of developers would be still newly certifying in 2018 and 15% in 2019 and applied the proportions respectively. We estimated the cost of development and preparation costs to be between $5,512.50 and $11,025 for 2018 and $2,362.50 and $4,725 for 2019. We calculated the cost per month for years 2018 and 2019 and using the high point estimates, estimated the development and preparation costs over a 6 to 12 month period between August 2018 to August 2019 to be between $4,068.75 and $6,825.

To calculate the cost for testing for this criterion, we multiplied the 5 developers that we estimated in the 2015 Edition to develop products to this criterion by our estimated cost to test per criterion of $475. The estimated cost per criterion was based on what one ONC–ATL charged for testing and averaged per criterion. To be conservative in our calculations, we reduced the number by 10% and 5% respectively resulting in $2,137.50 and $2,256.25.

Taking these estimated costs into account we expect cost savings to

remove the 2015 Edition ''drug formulary and preferred drug list checks'' criterion to be between $8,962.50 and $9,081.25.

1.4.3 Smoking Status

We propose to remove the 2015 Edition ''smoking status'' criterion (§ 170.315(a)(11)), which would include removing it from the 2015 Edition Base EHR definition. To calculate the cost savings for removing this criterion, we used the 2015 Edition estimated costs of developing and preparing the criterion to the 2015 Edition, between $15,750 and $31,500 and estimated that 35% of developers would be newly certified in 2018 and 15% in 2019. We estimated the cost of development and preparation costs to be between $5,512.50 and $11,025 for 2018 and $2,362.50 and $4,725 for 2019. We calculated the cost per month for years 2018 and 2019 and using the high point estimates, estimated the development and preparation costs over a 6 to 12 month period between August 2018 and August 2019. We estimated the costs to be between $4,068.75 at 6 months and $6,825 at 12 months.

To calculate the cost for testing for this criterion, 5 developers were estimated in the 2015 Edition to develop products to this criterion. We multiplied the 5 developers by our estimated cost to test per criterion of $475. This estimated cost per criterion was based on what one ONC–ATL charged for testing and averaged per criterion. To be conservative, we reduced the number by 10% and 5% respectively resulting in $2,137.50 and $2,256.25.

Taking these estimated costs into account we expect cost savings to remove the 2015 Edition ''smoking status'' criterion to be between $8,962.50 and $9,081.25.

1.4.4 Patient-Specific Education Resources

We propose to remove the 2015 Edition ''patient-specific education resources'' certification criterion (§ 170.315(a)(13)). To estimate the cost of removing this criterion, we used the 2015 Edition estimated costs for development and preparation which is between $4,709,880 and $6,279,840. We believe that 35% of developers would be still newly certifying in 2018 and 15% in 2019 and applied the proportions respectively. We estimated the cost of development and preparation to be between $1,648,458 and $2,197,944 for 2018 and $706,482 and $941,976 for 2019. We calculated the cost per month for years 2018 and 2019 and using the high point estimates, estimated the development and preparation costs over a 6 to 12 month period, within August 2018 to August 2019. We estimated the costs to be between $850,395 at 6 months and $1,360,632 at 12 months. To calculate the testing cost for this criterion, we multiplied the estimates from the 2015 Edition of 249 developers that we estimated would develop products to this criterion by our estimated cost to test per criterion of $475. The estimated cost per criterion was based on what one ONC–ATL charged for testing and averaged per criterion. To be conservative, we reduced the number by 10% and 5% respectively resulting in $106,447.50 and $112,361.25. Taking these estimated costs into account, we expect the cost savings of removing the 2015 Edition ''Patient-specific education resources'' criterion to be between $1,467,079.50 and $1,472,993.25.

1.4.5 Secure Messaging

We propose to remove the 2015 Edition ''secure messaging'' criterion (§ 170.315(e)(2)). To estimate the cost savings of removing this criterion, we used the estimates from the 2015 Edition final rule for development and preparation costs which is between $1,552,320 and $3,104,640. We estimated that 35% of developers would be still newly certifying in 2018 and 15% in 2019 and applied the proportions respectively. We estimated the cost of development and preparation costs to be between $543,312 and $1,086,624 for 2018 and $232,848 and $465,696 for 2019. We then calculated the cost per month for years 2018 and 2019 and using the high point estimates, estimated the development and preparation costs over a 6 to 12 month period, between August 2018 to August 2019 to be between $401,016 at 6 months and $672,672 at 12 months. To calculate the cost for testing this criterion, we multiplied the 246 developers that we estimated in the 2015 Edition would develop products to this criterion by our estimated cost to test per criterion of $475. The estimated cost per criterion was based on what one ONC–ATL charged for testing and averaged per criterion. To be conservative, we reduced the number by 10% and 5%, respectively, resulting in $105,165 and $111,007.50. Taking these estimated costs into account, we estimate the cost savings of removing the 2015 Edition ''Secure messaging'' criterion to be between $777,837 and $783,678.50.

1.5 Removal of Certain Certification Requirements

We propose to remove § 170.523(k)(1)(iii)(B), which requires ONC–ACBs to ensure that certified health IT includes a detailed description of all known material information concerning limitations that a user may encounter in the course of implementing and using the certified health IT, whether to meet ''meaningful use'' objectives and measures or to achieve any other use within the scope of the health IT's certification. We also propose to remove § 170.523(k)(1)(iv)(B) and (C), which state that the types of information required to be disclosed include but are not limited to: (B) Limitations, whether by contract or otherwise, on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification; or in connection with any data generated in the course of using any capability to which health IT is certified; (C) Limitations, including but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified.

To calculate the savings related to removing these two disclosure requirements, we estimated 830 products certified to the 2015 Edition. We did so by applying the market consolidation rate of −23.2% which was the rate observed between 2011 and 2014 Editions. Assuming that an ONC–ACB spends 1 hour on average reviewing costs, limitations and mandatory disclosures, we estimate the time saved by no longer having to review the limitations to be two-thirds of an hour. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30 and we assume this to be the hourly rate for an ONC–ACB reviewer. We multiplied 830, the projected number of certified products, by two- thirds of an hour and the assumed hourly rate and calculated the cost savings to be $48,859.

(2) Updates to the 2015 Edition Certification Criteria

The following section details the costs and benefits for updates to the 2015 Edition health IT certification criteria, which includes (1) costs and benefits to update certain 2015 Edition criteria to due to the adoption of the United States Core Data for Interoperability (USCDI) as a standard and (2) costs for new 2015 Edition criteria for electronic health

information export, API, privacy and security, and Data Segmentation for Privacy (DS4P)-Send and Data Segmentation for Privacy-Receive, and consent management for APIs.

2.1 United States Core Data for Interoperability

In order to advance interoperability by ensuring compliance with new structured data and code sets that support the data, we propose in this proposed rule to remove the ''Common Clinical Data Set'' definition and its references from the 2015 Edition and replace it with the ''United States Core Data for Interoperability'' (USCDI) standard, naming Version 1 (v1) in § 170.213 and incorporating it by reference in § 170.299. The USCDI v1 establishes a minimum set of data classes (including structured data) that are required for health IT to be interoperable nationwide and is designed to be expanded in an iterative and predictable way over time.

The USCDI v1 adds 2 new data classes, ''Clinical Notes'' and ''Provenance'' that were not defined in the CCDS, which will require updates to the Consolidated Clinical Document Architecture (C–CDA) standard and updates to the following certification criteria: § 170.315(b)(1) (transitions of care); (e)(1) (view, download, and transmit to 3rd party); (g)(6) (Consolidated CDA creation performance); (f)(5) (transmission to public health agencies—electronic case reporting); and (g)(9) (application access—all data request). From our analysis of the C–CDA standard, we conclude that the requirements of ''Provenance'' data class are already met by the existing C–CDA standard, and will not require any new development. Therefore, we have estimated the proposed cost to health IT developers to add support for ''Clinical Notes'' data class in C–CDA, and the necessary updates to the affected certification criteria. These estimates are detailed in Table 7 below and are based on the following assumptions:

1. *Health IT developers will use the same labor costs and data models.* Table 7 shows the estimated labor costs per product for a health IT developer to develop support for the additional USCDI data element in the C–CDA standard and affected certification criteria. We recognize that health IT developer costs will vary; however, our estimates in this section assume all health IT developers will incur the costs noted in Table 7.

2. *A proxy is needed to project the number of 2015 Edition certified health IT products.* We estimate that 545 products from 458 developers will be affected by our proposal. Our proxy is based on the number of 2014 Edition certified health IT products that are capable of recording patient data.[160] There were 710 products by 588 developers with at least one 2014 Edition product capable of recording patient data. We then multiplied these numbers by our certified health IT market consolidation estimates of −22.1% and −23.2% to project the number of 2015 developers and products, respectively.

3. According to the May 2016 BLS occupational employment statistics, the mean hourly wage for a ''Software Developer'' is $50.14.[161]

TABLE 7—COSTS TO HEALTH IT DEVELOPERS TO DEVELOP SUPPORT FOR THE ADDITIONAL USCDI DATA ELEMENT IN C–CDA STANDARD AND AFFECTED CERTIFICATION CRITERIA

[2016 Dollars]

Tasks	Details	Lower bound hours	Upper bound hours	Remarks
Update C–CDA creation)	New development to support ''Clinical Notes'' for C–CDA and C–CDA 2.1 Companion Guide.	800	1,800	(1) Lower bound assumes health IT already has developed C–CDA R2.1 into their system and only needs to be updated for new data class. (2) Upper bound estimates effort for organizations that are on older versions of C–CDA standard, for example C–CDA R1.1.
§ 170.315(b)(1) (transitions of care)	New development to support ''Clinical Notes'' for C–CDA and C–CDA 2.1Companion Guide.	200	600	Necessary updates to health IT to support the new data class to meet the criteria requirements.
§ 170.315(b)(6) (data export)	New development to support ''Clinical Notes'' for C–CDA and C–CDA 2.1 Companion Guide.	300	800	Necessary updates to health IT to support the new data class to meet the criteria requirements.
§ 170.315(e)(1) (view, download, and transmit to 3rd party).	New development to support ''Clinical Notes'' for C–CDA and C–CDA 2.1Companion Guide.	400	1,000	Necessary updates to health IT to support the new data class to meet the criteria requirements.
§ 170.315(g)(6) (Consolidated CDA creation performance).	New development to support ''Clinical Notes'' for C–CDA and C–CDA 2.1 Companion Guide.	200	600	170.315(b)(1) and § 170.315(g)(6) are related and may be developed together.
Total Hours		1,900	4,800	
Hourly Rate		$100.28		
Cost per Product		$190,532	$481,344	
Total Cost (545 products)		$103.8M	$262.3M	

[160] We defined ''products capable of recording patient data'' as any 2014 Edition health IT product that was certified for at least one of the following criteria: Demographics ((a)(5)), Medication List ((a)(7)), Medication Allergy List ((a)(8)), Problem List ((a)(6)), and Family Health History ((a)(12)).

[161] *https://www.bls.gov/oes/2016/may/oes439061.htm.*

We estimate that the cost to a health IT developer to develop support for the additional USCDI data element would range from $190,532 to $481,344. Therefore, assuming 545 products, we estimate that the total annual cost to all health IT developers would, on average, range from $103.8 million to $262.3 million. This would be a one-time cost to developers per product that is certified to the specified certification criteria and would not be perpetual.

We believe this proposal would benefit health care providers, patients, and the industry as a whole. Clinical notes and provenance were included in the draft USCDI v1 based on significant feedback from the industry, which highly regarded their desirability as part of interoperable exchanges. The free text portion of the clinical notes was most often relayed by clinicians as the data they sought, but were often missing during electronic health information exchange. Similarly, the provenance of data was also referenced by stakeholders as a fundamental need to improve the trustworthiness and reliability of the data being exchanged. We expect improvements to interoperable exchange of information and data provenance to significantly benefit providers and patients. However, we are not aware of an approach for quantifying these benefits and welcome comments on potential approaches to quantifying these benefits.

2.2 Electronic Health Information Export

We have proposed a new 2015 Edition certification criterion for ''electronic health information export'' in § 170.315(b)(10). The intent of this criterion is to provide patients and health IT users a means to efficiently export the entire electronic record for a single patient or all patients in a computable, electronic format. Further, it would facilitate the receiving health IT system's interpretation and use of the EHI to the extent reasonably practicable using the health IT developer's existing technology. This outcome would promote exchange, access, and use of electronic health information. It would also facilitate health care providers' ability to switch health IT systems or migrate electronic health information for use in other technologies. This proposed criterion supports two specific use cases. First, it supports the export for a single patient that would need to be enabled upon valid request from a user or a patient. Second, the EHI export functionality for all patients' data would support a health care provider or health system in switching health IT systems.

Costs

This section describes the estimated costs of the ''electronic health information export'' certification criterion. The cost estimates are based on the following assumptions:

1. *Health IT developers will use the same labor costs and data models.* Table 8 shows the estimated labor costs per product for a health IT developer to develop and maintain the electronic health information export functionality. We recognize that health IT developer costs will vary; however, our estimates in this section assume all health IT developers will incur the costs noted in Table 8.

2. *A proxy is needed to project the number of 2015 Edition certified health IT products containing the ''electronic health information export'' certification criterion.* We estimate that 545 products from 458 developers will contain the ''electronic health information export'' criterion. To develop these estimates we first identified a proxy for the number of health IT developers that may create a 2015 Edition certified health IT product containing the ''electronic health information export'' criterion. Our proxy is based on the number of 2014 Edition certified health IT products that are capable of recording patient data.[162] We based our estimates on these products because data must be captured to be exported under the proposed criterion. There were 710 products by 588 developers with at least one 2014 Edition product capable of recording patient data. We then multiplied these numbers by our certified health IT market consolidation estimates of −22.1% and −23.2% to project the number of 2015 developers and products, respectively.

3. According to the May 2016 BLS occupational employment statistics, the mean hourly wage for a ''Software Developer'' is $50.14.[163]

TABLE 8—ESTIMATED LABOR COSTS TO DEVELOP AND MAINTAIN THE ELECTRONIC HEALTH INFORMATION EXPORT CRITERION PER PRODUCT

Activity	Lower bound hours	Upper bound hours	Remarks
Task 1: Developing the Data Dictionary and exporting the EHI in a developer format (per product).	160	1,600	This is the effort to document all the data exported by the product for a single patient and for all patients. The lower bound assumes that the health IT developer already has a standard format in which they are exporting the data for either case (*e.g.,* C–CDA for single patient, CSV file or database dump for all data) and the effort is merely to publish it to the users. On the other hand, the upper bound reflects the case where the health IT has to develop the export capability de novo into their product, and document the data output. This still assumes that the developer will be able to use the format of their choice. *Note: This is a one-time cost to develop the export capability.*
Task 2: Maintaining the Data Dictionary and performing export when requested (per product).	80	800	This is the annual maintenance cost charged by health IT developers to provide C–CDA feed to providers. This is a yearly update to products that are typically modest. The lower bound estimate assumes the effort when there are only minor changes to the product. The upper bound estimate assumes the effort when the product supports a substantial number of new data classes.

[162] We defined ''products capable of recording patient data'' as any 2014 Edition product that was certified for at least one of the following criteria: Demographics ((a)(5)), Medication List ((a)(7)), Medication Allergy List ((a)(8)), Problem List ((a)(6)), and Family Health History ((a)(12)).

[163] *https://www.bls.gov/oes/2016/may/oes439061.htm.*

TABLE 8—ESTIMATED LABOR COSTS TO DEVELOP AND MAINTAIN THE ELECTRONIC HEALTH INFORMATION EXPORT CRITERION PER PRODUCT—Continued

Activity	Lower bound hours	Upper bound hours	Remarks
Task 3: Maintaining the software to perform the electronic health information export (per product).	80	800	This is the annual cost to update the software that would generate the data access files. The lower bound estimates the cost to maintain the software when there are minor changes to the product, including updates to underlying software (*e.g.,* database versions, operating systems, etc.). The upper bound estimate accounts for substantial reworking of the export software program to support new data classes or new data formats.
Total Labor Hours	320	3,200	

TABLE 9—EXAMPLE CALCULATION FOR THE LOWER BOUND ESTIMATED COST TO HEALTH IT DEVELOPERS TO PERFORM TASK 1 FOR THE ELECTRONIC HEALTH INFORMATION EXPORT CRITERION

[2016 Dollars]

	Estimated labor hours lower bound	Developer salary (per hour)	Projected products
Task 1	160	$100.28	545

Example Calculation:

160 hours × $100.28 × 545 products = $8,744,416.

TABLE 10—TOTAL COST TO DEVELOP AND MAINTAIN THE ELECTRONIC HEALTH INFORMATION EXPORT CRITERION

[2016 Dollars]

Activity	Estimated cost	
	Lower bound	Upper bound
Task 1 (545 products)	$8,744,416	$87,444,160
Task 2 (545 products)	4,372,208	43,722,080
Task 3 (545 products)	4,372,208	43,722,080
Total (545 products)	17,488,832	174,888,320

Based on the stated assumptions and costs outlined in Table 8, the total estimated cost for health IT developers to develop products to the electronic health information export certification criterion will range from $17.5 million to $174.9 million. Assuming 458 health IT developers, there would be an average cost per health IT developer ranging from $38,185 to $381,852. The midpoint of ranges stated is used as the primary estimate of costs and benefits. We note that the development costs, which equal half of the total, would be a one-time cost and would not be perpetual.

Benefits

There are a number of benefits to the electronic health information export functionality. In our analysis, we have calculated the benefits in terms of the reduced costs of the electronic health information export functionality compared to performing data export without the electronic health information export functionality. The benefit calculations below are based on the following assumptions:

1. *On average, 5% of providers and hospitals switch their health IT annually.* Using CMS Medicare EHR Incentive Program data from years 2013–2016, we estimate the rate of providers (hospitals and eligible professionals) that changed their health IT developer. We believe that the electronic health information export functionality would help alleviate the burden of switching between health IT systems by making data more portable. Thus, the benefit calculations are based on assumptions regarding the number of clinical practices (n = 4,774) and hospitals (n = 226) that are projected to switch products in a year.

2. *Health IT consultants*[164] *will use the same labor costs and data models.* Table 11 shows the estimated labor costs per product for a hospital or health care provider to hire a health IT consultant to perform data export without the electronic health information export functionality. We recognize that these costs will vary based on the size of the hospital or clinical practice.

3. According to the May 2016 BLS occupational employment statistics, the mean hourly wage for a ''Software Developer'' is $50.14.[165]

[164] ''Health IT consultant'' refers to a technical expert that a hospital or provider will hire to migrate their data from a legacy system to a new EHR.

[165] *https://www.bls.gov/oes/2016/may/oes439061.htm.*

TABLE 11—COST PER PROVIDER TO PERFORM DATA EXPORT WITHOUT ELECTRONIC HEALTH INFORMATION EXPORT FUNCTIONALITY WHEN SWITCHING HEALTH IT PRODUCTS

Activity	Estimated cost per health IT switch (lower bound) (hour)	Estimated cost per health IT switch (upper bound) (hour)	Remarks
Task 1: Understanding and mapping the data in health IT database into standard terms.	320	3,200	The lower bound is an estimate for a small provider practice using the standard instance of a certified health IT product with no customization and use of nationally recognized content standards. The upper bound estimates a medium to large practice with substantial local customization of content.
Task 2: Exporting the data from the health IT into a format that can be subsequently used to import.	160	1,600	The lower bound assumes that the certified health IT product is capable of exporting most of the data into standard output format such as C–CDA. The upper bound estimates the case where a large amount of data is not easily exported by the certified health IT product and therefore substantial one-off software needs to be written to export the data into a custom (de novo) format developed for the transition.
Total Labor Hours	480	4,800	

Table 12 provides an example calculation for how we calculated our total costs presented in table 13.

TABLE 12—EXAMPLE CALCULATION FOR THE LOWER BOUND ESTIMATED COST TO PROVIDERS TO HIRE A HEALTH IT CONSULTANT TO PERFORM TASK 1 WITHOUT THE ELECTRONIC HEALTH INFORMATION FUNCTIONALITY

[2016 Dollars]

	Estimated labor hours lower bound	Developer salary (per hour)	Estimated annual number of health IT switches
Task 1	320	$100.28	5,000

Example Calculation

320 hours × $100.28 × 5,000 switches = $160,448,000

TABLE 13—TOTAL COST TO PROVIDERS TO PERFORM DATA EXPORT WITHOUT THE ELECTRONIC HEALTH INFORMATION EXPORT FUNCTIONALITY WHEN SWITCHING HEALTH IT PRODUCTS

[2016 Dollars]

Activity	Estimated cost	
	Lower bound	Upper bound
Task 1	$160,448,000	$1,604,480,000
Task 2	80,224,000	802,240,000
Total Cost Savings (5,000 switches)	240,672,000	2,406,720,000

We multiplied the costs to switch health IT by the estimated number of hospitals and clinical practices affected. Thus the estimated annual benefit, in terms of cost savings to hospitals and clinical practices would range from $240.7 million to $2.4 billion. If we assume, based on our upper bound estimates above, that the total cost to health IT developers is $174.9 million and that increased developer costs are passed to customers, then the net benefit to hospitals and clinical practices would range from $65.8 million to $2.2 billion. The midpoint of ranges stated is used as the primary estimate of costs and benefits.

2.3 Application Programming Interfaces

Our proposals regarding APIs in this proposed rule reflect the full depth and scope of what we believe is necessary to implement the API Condition of Certification. We propose to include new standards, new implementation specifications, and a new certification criterion. Our proposal also includes a detailed Condition of Certification and associated Maintenance of Certification requirements, as well as a proposal to modify the Base EHR definition.

Costs

This section describes the potential costs of the API certification criterion. The cost estimates below are based on the following assumptions:

1. *Health IT developers will use the same labor costs and data models.* Table 14 shows the estimated labor costs per

product for a health IT developer to develop and maintain an API. We recognize that health IT developer costs will vary; however, we have assumed in our calculations that all health IT developers will incur the costs noted in Table 14.

2. *A proxy is needed to project number of 2015 Edition certified health IT products containing the API certification criterion.* We estimate that 459 products from 394 developers will contain the API criterion. We used a proxy to determine the number of health IT developers that may develop an API for the certification to the 2015 edition. There were 598 products and 506 developers with at least one 2014 Edition certified health IT product that could perform transitions of care. We then multiplied this number by our certified health IT market consolidation estimates of −22.1% and −23.2% to project the number of 2015 developers and products, respectively. We believe this estimate serves as a reasonable proxy for products capability of sending patient data. The 2015 Edition required API functionality achieves a similar end by allowing providers to retrieve patient data from secure data servers hosted by other developers, as well as providing patients access to their medical records through third-party applications connected to these same secure servers.

3. According to the May 2016 BLS occupational employment statistics, the mean hourly wage for a ''Software Developer'' is $50.14.[166]

TABLE 14—ESTIMATED LABOR HOURS TO DEVELOP AND MAINTAIN API

Tasks	Details	Estimated labor hours		Remarks
		Lower bound	Upper bound	
Task 1: Develop support for Fast Healthcare Interoperability Resources (FHIR®) API and ARCH 1.0 (per product).	(1) New development to support ''Clinical Notes'', ''Provenance'', ''Address'' and ''Telecon''. (2) Only ''Mandatory'' and ''Must Support'' elements are required for each of the ARCH resources.	1,500	3,500	(1) Lower bound assumes health IT already has developed FHIR DSTU2 and SMART for 2015 and only needs to be updated for additional resources. (2) Upper bound assumes new development for all resources.
Task 2: Development of App registration Server and Portal (per developer).	(1) New registration server development (or updates to existing server) to support registration timeliness and publication of FHIR endpoints. (2) Development of portal and managing the application registration system.	1,000	2,500	(1) Lower bound assumes that the developer already has existing application registration infrastructure in place, and only needs to update it to support the API Maintenance of Certification requirements. (2) Upper bound is new development of an application registration service and portal.
Task 3: Update ARCH and FHIR standards as part of regular API maintenance (per product).	(1) This is an estimate for adding one or two new data elements to USCDI and making it a requirement. (2) Support for API-enabled services for data on a single patient and multiple patients, as well as SMART Backend Services as part of FHIR 4.	1,200	2,000	(1) Lower bound assumes developers are already supporting the elements and also have been testing API-enabled services for data on a single patient and multiple patients. (2) Upper bound assumes new development for USCDI updates and API-enabled services for data on a single patient and multiple patients.
Task 4: Update Application Registration Server and Portal (per developer).	This would be yearly updates and maintenance of the portal to keep it running. We do not anticipate any major changes to the standard and will be primarily driven by usage and developer interest.	400	1,300	(1) Lower bound estimates hours to keep it running with junior staff. (2) Upper bound estimates small updates and adds in developer and quality assurance resources.
Other costs (50% per product, 50% per developer).	(1) Server costs. (2) Software costs (*e.g.,* databases, application servers, portal technology).	$5,000	$25,000	(1) Estimated as monetized costs and not as hours; most of the costs would be one-time procurement costs plus yearly maintenance. *Note: One-time cost.*

Table 15 provides an example calculation for how we calculated our total costs presented in Table 16.

[166] *https://www.bls.gov/oes/2016/may/oes439061.htm.*

TABLE 15—EXAMPLE CALCULATION FOR THE LOWER BOUND ESTIMATED COST TO DEVELOPERS TO PERFORM TASK 1 TO DEVELOP API

[2016 Dollars]

	Estimated labor hours lower bound	Developer salary (per hour)	Projected products
Task 1	1,500	$100.28	459

Example Calculation:
1,500 hours × $100.28 × 459 products = $69,042,780

TABLE 16—TOTAL COST TO DEVELOP AND MAINTAIN API

[2016 Dollars]

Activity	Estimated cost	
	Lower bound	Upper bound
Task 1 (459 products)	$69,042,780	$161,099,820
Task 2 (394 developers)	39,510,320	98,775,800
Task 3 (459 products)	55,234,224	92,057,040
Task 4 (394 developers)	15,804,128	51,363,416
Other Costs (394 developers)	985,000	4,925,000
Other Costs (459 products)	1,147,500	5,737,500
Total (459 products and 394 developers)	181,723,952	413,958,576

We note that we have proposed to adopt in § 170.404(b)(3) a specific requirement that an API Technology Supplier must support the publication of Service Base URLs for all of its customers regardless of whether they are centrally managed by the API Technology Supplier or locally deployed. The API Technology Supplier must make such information publicly available at no charge. Thus, we are placing the responsibility of publishing the URLs on health IT developers and those costs are captured in the registration portal cost estimation in this RIA.

Based on the stated assumptions and costs outlined in Table 16, the total estimated costs for health IT developers to develop and maintain a product to the API criterion would range from $181.7 million to $414.0 million with an average cost per developer ranging from $461,228 to $1,050,656. We note that the ''other costs,'' which account for $2.1 million to $10.7 million of this total are one-time costs and are not perpetual. The midpoint of ranges stated is used as the primary estimate of costs and benefits.

Benefits

The Medicare Access and CHIP Reauthorization Act (MACRA) tasks ONC with measuring interoperability in the health IT industry.[167] The measurement concepts developed include a multi-part approach analyzing not only adoption of health IT functionalities supporting information exchange but the downstream impact of these technologies on data completeness, data integration, and supports for core functions of patient care. The benefits of our API proposal are similarly multifaceted. In the analysis below, we quantify benefits in the following three areas:

- Reduction in provider burden associated with locating patient data;
- Reduced costs related to reductions in duplicate lab tests, readmissions, emergency room (ER) visits, and adverse drug events due to increased interoperability. We focused on these outcomes for two reasons: (i) Evidence in literature indicates that health information exchange impacts the chosen measures; and (ii) cost of care associated with these measures is high and the impact of health information exchange is likely to result in significant benefits in the form of cost reduction.
- Increase in the number of individuals with access to their health information.

[167] Health IT Buzz Blog, *Measuring Interoperability: Listening and Learning, https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/interoperability-electronic-health-and-medical-records/measuring-interoperability-listening-learning/.*

The benefit calculations are based on the following assumptions:

1. *Benefits noted in academic literature are assumed accurate.* Estimates of the benefits are based on estimates obtained from peer reviewed academic literature. ONC reviewed academic articles for validity; however, models were not replicated.

2. *Hospitals and eligible professionals that have participated in the CMS EHR Incentive Programs will be impacted:* Estimates are based on the assumption that 439,187 health care providers and/or 4,519 hospitals would be affected by this regulatory action.

3. *Estimates on the impact of APIs on rates of interoperability (1% to 4%) are based on ONC analysis.* To identify the impact of the API proposal on interoperability, we used regression analysis. Specifically, we estimated linear probability models that identified the impact of 2014 Edition certified EHR on hospitals' interoperability (whether a hospital sends, receives, finds, and integrates summary of care records). Using data from the American Hospital Association (AHA) from years 2014 to 2015 in the model, we controlled for hospital size, profit status, participation in a health information organization, and state and year fixed effects. The marginal effect of using a 2014 Edition certified health IT equated to a 5% increase in interoperability. This is an upper bound estimate. For the purpose

of this analysis, we assume that one to four percentage points would be a reasonable range for API's marginal impact on interoperability.

As noted previously, there might be shared benefits across certain proposals and we have taken steps to ensure that the benefits attributed to each proposal are unique to the proposal referenced. Specifically, we used regression analysis to calculate the impact of our real world testing and API proposals on interoperability. We assumed that the collective impact of real world testing and API proposals on interoperability would not exceed the impact of 2014 Edition certified health IT. Therefore, we estimated linear probability models that identified the impact of 2014 Edition certified health IT on hospitals' interoperability.[168] We controlled for additional factors such as participation in a health information exchange organization, hospital characteristics, and urban/rural status. We found the marginal effect of using 2014 Edition certified health IT was a five percentage point increase in interoperability.

While we acknowledge that there might be shared benefits across proposals, we have taken steps to ensure that the benefits attributed to each proposal is unique to the proposal referenced. We assumed that this marginal effect is true for our proposals and distributed the 5% benefit across our real world testing and API proposals at (.1–1%) to (1–4%) respectively. Moreover, the number of providers impacted is proposal specific. Given data limitations, we believe this approach allows us to estimate the benefits of our proposals without double counting the impact each proposal might have on interoperability.

The first table below shows benefits of APIs for providers where we monetize the impact of APIs as total amount saved by reducing provider time spent with the health IT. Sinsky et al found physicians spend 27% of their total time on direct clinical face time with patients, and 49.2% of their time on EHR and desk work.[169] Outside office hours, physicians spend another 1 to 2 hours of personal time each night doing additional computer and other clerical work. Based on this study, we assume that providers spend, on average, 6 hours per day with their EHR (4 hours of an 8 hour work day and 2 hours outside of office hours). Despite the number of hours providers spend in their EHR, there is evidence that the introduction of EHRs is associated with time saved. Amusan et al found that EHR and computerized provider order entry (CPOE) implementation was associated with 3.69 minutes of time saved five months post implementation.[170] Additionally, Adler-Milstein et al found that an increase in EHR use resulted in a 5.3% increase in work relative value units per clinician work day.[171] Using this evidence, we estimate the potential impact of APIs on providers' time ranges from 1%–5%.[172] Because the benefit of time saved is not limited to interoperable exchange of health information among providers but includes additional benefits such as increased patient knowledge, we used evidence from the literature to calculate the time saved benefit. Thus, the impact of APIs on provider time is expected to represent a larger impact (5%) than the impact of APIs on health outcomes (1%–4%) and cost. This is primarily because provider behavior is more directly affected by this improvement.

Benefits of APIs

TABLE 17—BENEFIT OF API PROVIDERS

[2016 Dollars]

Benefit type	Number affected	Hourly wage	Hours saved (percent) [a b]		Hours per day with EHR	Number of working days in a year	Total benefit [c] (per year)	
			Min	Max			Min	Max
Reduction in provider time spent in health IT by improving usability and interoperability.	439,187 providers	95	1	5	[d] 6	260	$651M	$3.3B

[a] Julia Adler-Milstein and Robert S. Huckman, The Impact of Electronic Health Record Use on Physician Productivity, Am J Manag Care (Nov. 19, 2013).

[b] Amusan, Tongen, Speedie, and Mellin, A time-motion study to evaluate the impact of EMR and CPOE implementation on physician efficiency, J. Healthcare Inf. Manag. (Fall 2008), at 31–7.

[c] Total benefit is a product of *number affected physicians, hourly wage, hours saved from EHR improvements, hours worked with EHR,* and *number of working days in a year.*

[d] Christine Sinsky et al., *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties,* Ann Intern Med. (Dec. 6, 2016), at 753–60.

TABLE 18—BENEFIT OF API FOR PATIENTS AND PAYERS

[2016 Dollars]

Benefit type	Number affected	Overall interop impact (marginal effect)	Impact of API		Total cost	% of total cost impacted	Total benefit [a] (per year)	
			Min	Max			Min	Max
Duplicate testing	439,187 providers	[b] 0.09	0.01	0.04	[c] 200 Billion.	100	$180M	$720M
Avoidable hospitalizations and readmissions.	4,519 hospitals	[b] 0.09	0.01	0.04	[d] $41B	100	37M	148M

[168] American Hospital Association Health IT Supplement Survey, *http://www.ahadata.com/aha-healthcare-database/.*

[169] Christine Sinsky et al., *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties,* Ann Intern Med. (Dec. 6, 2016), at 753–60.

[170] Amusan, Tongen, Speedie, and Mellin, A time-motion study to evaluate the impact of EMR and CPOE implementation on physician efficiency, J. Healthcare Inf. Manag. (Fall 2008), at 31–7.

[171] Julia Adler-Milstein and Robert S. Huckman, The Impact of Electronic Health Record Use on Physician Productivity, Am J Manag Care (Nov. 19, 2013).

[172] The calculation for these estimates are as follows: 1% leverages Amusan et al.'s lower bound estimate of 3.69 minutes. Assuming 6 hours (or 360 minutes) per day, this amounts to approximately 1% of time saved. The upper bound estimate of 5% leverages Adler-Milstein's estimate of a 5.3% estimate (rounded to 5%).

TABLE 18—BENEFIT OF API FOR PATIENTS AND PAYERS—Continued

[2016 Dollars]

Benefit type	Number affected	Overall interop impact (marginal effect)	Impact of API		Total cost	% of total cost impacted	Total benefit [a] (per year)	
			Min	Max			Min	Max
E visits	100% of visits affected	[b] 0.09	0.01	0.04	[e] Cost per ER visit $1,233, 131M visits.	100	48M	194M
Adverse drug events	20% of events affected	[f] 22%	0.01	0.04	[g] $30 billion.	20	13M	53M

[a] Total benefit is a product of *total cost, % of total cost impacted, overall impact of interoperability, and impact of API.*

[b] Stephen E. Ross, Tiffany A. Radcliff, William G. Leblanc, L. Miriam Dickinson, Anne M. Libby, and Donald E. Nease Jr., Effects of health information exchange adoption on ambulatory testing rates, J. Am. Med. Inform. Assoc. (2013), at 1137–1142; Bridget A. Stewart, Susan Fernandes, Elizabeth Rodriguez-Huertas, and Michael Landzberg, A preliminary look at duplicate testing associated with lack of electronic health record interoperability for transferred patients, J. of the Am. Med. Informatics Assoc. (2010), at 341–344; Sezgin Ayabakan, Indranil R. Bardhan, Zhiqiang (Eric) Zheng, and Kirk Kirksey Value of health information sharing in reducing healthcare waste: An analysis of duplicate testing across hospitals, MIS Quarterly (Jan. 1, 2017); Eric J. Lammers, Julia Adler-Milstein, and Keith E. Kocher, Does health information exchange reduce redundant imaging? Evidence from emergency departments, Med Care (Mar. 2014), at 227–34.

[c] National Academy of Medicine. (2016), *http://money.cnn.com/2017/05/20/news/economy/medical-tests/index.html.*

[d] Agency for Healthcare Research and Quality (AHRQ) Statistical Brief #199 (Dec. 2015), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb199-Readmissions-Payer-Age.pdf;* AHRQ Statistical Brief #72, Nationwide Frequency and Costs of Potentially Preventable Hospitalizations (Apr. 2009), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb72.pdf.*

[e] National Center for Health Statistics (NCHS) Data Brief No. 252 (June 2016), *https://www.cdc.gov/nchs/data/databriefs/db252.pdf;* Nolan Caldwell, Tanja Srebotnjak, Tiffany Wang, and Renee Hsia, ''How Much Will I Get Charged for This?'' Patient Charges for Top Ten Diagnoses in the Emergency Department (2013), *https://doi.org/10.1371/journal.pone.0055491.*

[f] M.F. Furukawa, W.D. Spector, M.R. Limcangco, and W.E. Encinosa, Meaningful use of health information technology and declines in in-hospital adverse drug events, J. of the Am. Med. Informatics Assoc. (2017).

[g] Janet Sultana, Paola Cutroneo, and Gianluca Trifirò, *Clinical and economic burden of adverse drug reactions.*

Based on the above calculations, we estimate the annual benefit to health care providers for the use of the proposed API capabilities would, on average, range from $651 million to $3.3 billion. We estimate the annual benefit for patients and payers would, on average, range from $278 million to million to $1.1 billion. Therefore, we estimate the total annual benefit of APIs to, on average, range from $929 million to $4.4 billion. If we assume, based on our cost estimates, an annual cost to health IT developers of $414 million and that increased developer costs are passed to customers, then the net benefit to hospitals/providers would range from $515 million to $3.3 billion. The midpoint of ranges stated is used as the primary estimate of benefits.

As we stated above, for Table 17, we assume APIs provide both patients and clinicians with increased access to EHI, which will have a direct impact on physicians by making their work more efficient. Extrapolating the numbers from literature, we assume this technology will improve physicians' time by 1%–5%. Also as stated above, for Table 18, we assume APIs affect utilization through marginal improvements in interoperability. For this reason, in addition to APIs, we needed to incorporate the impact of interoperability on each of the outcomes. We request comment on these assumptions. Specifically, whether they are appropriate and whether there are alternative assumptions or bases upon which we should make our assumptions.

We expect additional benefits from the use of APIs could be derived from increased patient, and eventually payer, access to EHI. APIs make it easier for patients to transmit data to and from different sources. According to the Health Information National Trends Survey,[173] half of Americans were offered access to an online medical record by a provider or insurer in 2017. However, among those who were offered access, only 53% accessed their record at least once within the last year, and only 3.6% of individuals who accessed their record reported transmitting their data to a service or application. The proportion of individuals accessing their online health information and transmitting their information to third parties is expected to grow as APIs become more widespread and make more data available in a computable format. Growing evidence suggests that patients who have access to their EHI are more likely to adhere to medical orders including screening recommendations.[174] Thus, we expect such patients would ultimately realize improved health outcomes.

In addition, the use of APIs to support the exchange and analysis of payment related data (including price information) would improve cost transparency in the market, increase the availability of valuable information for payers and patients, and likely drive down health care prices. For instance, a recent study by the Minnesota Department of Health showed that the pricing for knee replacement surgery, which is a standard procedure in many hospitals, can vary significantly across practices in the same locality. The Minnesota study showed that Minnesota insurers paid as much as $47,000 for a patient's total knee replacement and as little as $6,200—a nearly eight-fold price difference. In addition to total knee replacements, the study found that total hip replacement costs ranged from $6,700 to $44,000, a 6½-fold difference. Typical vaginal baby delivery ranged from $2,900 to $12,300, while C-section deliveries ranged from $4,700 to $22,800. Another study by Premier in conjunction with Wake Forest University Medical Center found similar results. Among 350 hospitals, the average cost of primary knee implants was $4,464. Yet, 50% of the hospitals paid between $4,066 and $5,609 on the devices. Further, the same group of hospitals paid an average of $5,252 for primary hip implants, but 50% of the hospitals paid between $4,759 and $6,463. The studies illustrated the secretive nature of pricing in the health care market, as well as the extreme variations in price that can exist for the same procedure within the same locality.[175] [176] While this study was the

[173] These estimates were derived from Health Information National Trends Survey 5, Cycle 1 (2017).

[174] *See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5391175/.*

[175] Glenn Howatt, *That surgery will cost you $6,200. Or maybe $47,000,* Star Tribune (Jan. 3, 2018), *available at http://www.startribune.com/that-surgery-will-cost-you-6-200-or-maybe-47-000/467894173/.*

[176] Bakalar, Catherine and Czajka, Robin (2018) Margin of Excellence: Total Joint Replacements

first-ever local study of insurance company payments to hospitals for those four common procedures, similar pricing variations have been well documented in other, broader studies in recent years.[177] We expect that making such price information available to insurers through APIs would drive health care prices down, which could lead to significant benefits across the health care continuum.

While the examples above emphasize procedures that tend to have defined end points, the eventual population health queries would more broadly allow payers and analytics firms working for employers to computationally examine the care providers render. Not only is price transparency currently missing from the marketplace, but for most inpatient care, the actual details of care are largely unobtainable through any APIs. However, we are not aware of an approach for quantifying these types of benefits and welcome comments on potential approaches to quantifying these benefits.

2.4 New Privacy and Security Certification Criteria

To be certified to the new privacy and security certification criteria, encrypt authentication credentials (§ 170.315(d)(12)) and multi-factor authentication (MFA) (§ 170.315(d)(13)), we are proposing to require health IT developers to assess their Health IT Modules' capabilities and attest ''yes'' or ''no'' to the certification criteria. As specified in section IV.C.3 of this proposed rule, we are proposing to make these certification criteria applicable to all Health IT Modules under the Program. For encrypt authentication credentials and multi-factor authentication, we are proposing to require a simple attestation. For MFA, we are also proposing to require that if the health IT developer attests to supporting MFA, the health IT developer would need to explain how it supports MFA. We also request public comment on whether there is value in adopting an MFA criterion and whether the health IT developer should explain how it supports MFA.

Costs

These criteria are not intended to place additional burden on health IT developers as they do not require new development or implementation. Rather, a health IT developer is only required to attest to whether they encrypt authentication credentials or support MFA. We expect the costs associated with attesting to these criteria to be de minimis because we do not expect additional forms to be required and expect minimal effort would be required to complete the attestation. We welcome comments on these expectations. The midpoint of ranges stated is used as the primary estimate of costs and benefits.

Benefits

As stated previously, we are not requiring health IT developers to encrypt authentication credentials or support MFA. Instead, we are requiring they attest to whether they support the certification criteria or not. By requiring an attestation, we are promoting transparency, which might motivate some health IT developers that do not currently encrypt authentication credentials or support MFA to do so. If health IT developers are motivated by this criteria and ultimately do encrypt authentication credentials and/or support MFA, we acknowledge that there would be costs to do so; however, we assume that the benefits would substantially exceed the costs. Encrypting authentication credentials and adopting MFA would reduce the likelihood that authentication credentials would be compromised and would eliminate an unnecessary use of IT resources. Encrypting authentication credentials and adopting MFA could directly reduce providers' operating/support costs, which would reduce their administrative and financial burden. Encrypting authentication credentials would also help decrease costs and burden by reducing the number of password resets due to possible phishing or other vulnerabilities.

According to Verizon's 2017 Data Breach Investigations Report, 81% of hacking-related breaches leveraged either stolen and/or weak passwords.[178] The Verizon report encourages customers to vary their passwords and use two-factor authentication. Also, NIST Special Publication 800–63B: Digital Identity Guidelines, *Authentication and Lifecycle Management,*[179] recommends the use of and provides the requirements for using multi-factor authenticators. Based on these reports and other anecdotal evidence, we believe encrypting authentication credentials and supporting MFA are established best practices among industry developers, including health IT developers. As described above, we propose to require health IT developers to attest to whether they encrypt authentication credentials. We do not have access to published literature that details how health IT developers are already encrypting authentication credentials and supporting MFA industry-wide, but we believe the majority of health IT developers, or around 80%, are taking such actions. We assume that building this functionality is in the future project plans for the remaining 20% because, as noted previously, adopting these capabilities is an industry best practice. Health IT developers that have not yet adopted these capabilities are likely already making financial investments to get up to speed with industry standards. We believe our proposal may motivate these health IT developers to speed their implementation process, but we have not attributed a monetary estimate to this potential benefit because our rule is not a direct cause of health IT developers adopting these capabilities. By the time we release the final rule, many more, or perhaps all, health IT developers will likely already be encrypting authentication credentials and supporting MFA. We welcome comments on this expectation and any means or methods we could use to quantify these benefits.

2.5 Data Segmentation for Privacy-Send and Data Segmentation for Privacy-Receive; and Consent Management for APIs

We propose to remove the current 2015 Edition Data Segmentation for Privacy (DS4P)-send (§ 170.315(b)(7)) and DS4P-receive (§ 170.315(b)(8)) certification criteria which apply the DS4P standard at the document level. We propose to replace these two criteria with three new 2015 Edition DS4P certification criteria (two for C–CDA and one for FHIR) that would support a more granular approach to privacy tagging data for health information exchange supported by either the C–CDA- or FHIR-based exchange standards. In place of the removed 2015 Edition DS4P criteria, we propose to adopt new DS4P-send (§ 170.315(b)(12)) and DS4P-receive (§ 170.315(b)(13))

[White Paper] May 24, 2018, *http://offers.premierinc.com/rs/381-NBB-525/images/WC_CM_TotalJoint_2018_05_04.pdf.*

[177] *See e.g.,* Elisabeth Rosenthal, *The $2.7 Trillion Medical Bill; Colonoscopies Explains Why U.S. Leads the World in Health Expenditures,* The New York Times (June 1, 2013), *available at http://www.nytimes.com/2013/06/02/health/colonoscopies-explain-why-us-leads-the-world-in-health-expenditures.html?pagewanted=all*; Steve Twedt, *Hospitals' charges can vary greatly for similar services,* Pittsburgh Post-Gazette (May 9, 2013), *available at http://www.post-gazette.com/business/businessnews/2013/05/09/Hospitals-charges-can-vary-greatly-for-similar-services/stories/201305090300.*

[178] *http://www.verizonenterprise.com/verizon-insights-lab/dbir/2017/.*

[179] *https://pages.nist.gov/800-63-3/sp800-63b.html.*

criteria that would remain based on the C–CDA and the HL7 DS4P standard. These criteria would include capabilities for applying the DS4P standard at the document, section, and entry level. We also propose to adopt a third 2015 Edition DS4P certification criterion ''consent management for APIs'' (§ 170.315(g)(11)) that requires health IT to be capable of responding to requests for data through an API in accordance with the Consent Implementation Guide. Our primary purpose for proposing to remove and replace them, in lieu of proposing to revise them, is to provide clarity to stakeholders as to the additional functionality enabled by health IT certified to the new criteria.

Costs

We anticipate this proposal could result in up-front costs to health IT developers as this new criteria would require the health IT to support all three levels—document, section, and entry—as specified in the current DS4P standard. However, we note that these criteria are not being required in any program at this time. As of the beginning of the third quarter of the 2018 CY, only about 20 products (products with multiple certified versions were counted once) were certified to the current 2015 Edition DS4P certification criteria. We estimate that 10–15 products will implement the new DS4P criteria. Developers may need to perform fairly extensive health IT upgrades to support the more complex and granular data tagging requirements under these criteria. We anticipate developers will need approximately 1,500–2,500 hours to upgrade databases and/or other backend infrastructure to appropriately apply security labels to data and/or develop access control capabilities. Moreover, developers will likely incur costs to upgrade health IT to generate a security-labeled C–CDA conforming to the DS4P standard. We estimate developers will need 400–600 hours per criterion to make these upgrades on systems that had previously certified to the document-level DS4P criteria, or 720–1,220 hours per criterion for systems that are implementing these criteria for the first time. We believe this work would be performed by a ''Software Developer.'' According to the May 2016 BLS occupational employment statistics, the mean hourly wage for software developer is $50.14. As noted previously, we have assumed that overhead costs (including benefits) are equal to 100% of pre-tax wages, so the hourly wage including overhead costs is $100.28. Therefore, we estimate the total cost to developers could range from $2,306,440 to $7,430,748. We note that this would be a one-time cost. The midpoint of ranges stated is used as the primary estimate of costs and benefits.

Additionally, our proposal supports the capability to respond to requests for patient consent information through an API compatible with FHIR Release 3. In order to meet the ''consent management for APIs'' criteria, developers would demonstrate compatibility with the standards framework used for the Consent Implementation Guide. We have estimated costs associated with this aspect of our proposal using the following assumptions:

1. We estimate developers will require 1,500–3,500 hours to upgrade health IT to align with the FHIR STU3 data model and develop a STU3 compatible FHIR server.

2. As with the two DS4P criteria, we anticipate developers will need approximately 1,500–2,500 hours to upgrade databases and/or other backend infrastructure to appropriately apply security labels to data and/or develop access control capabilities. We expect that this would be a one-time cost.

3. Because certification to this criterion is voluntary and because supporting this criterion requires implementation of a version of FHIR (STU3) that does not align with the other API criterion in this rule (based on DSTU2), we estimate the number of products that will support this criterion is approximately 5% of the total number of 2015 certified products. We used a proxy to determine the number of health IT developers that may develop an API for the 2015 Edition. There were 598 products and 506 developers with at least one 2014 Edition certified product that could perform transitions of care. We then multiplied this number by our certified health IT market consolidation estimates of −22.1% and −23.2% to project the number of 2015 developers and products, respectively; we estimate that 459 products from 394 developers will contain the API criterion. Therefore, we anticipate 23 products from 20 developers will certify to the ''consent management for APIs'' criterion. We believe this work would be performed by a ''Software Developer.''

4. According to the May 2016 BLS occupational employment statistics, the mean hourly wage for a ''Software Developer'' is $50.14.

Our cost estimates are explained in the table below.

TABLE 19—COSTS RELATED TO DATA SEGMENTATION FOR PRIVACY USING API

[2016 Dollars]

Tasks	Details	Lower bound hours	Upper bound hours	Assumptions	Remarks
Task 1: Enhance health IT to align with the FHIR STU3 data model and develop a STU3 compatible FHIR server.	Enhance health IT to align with the FHIR STU3 data model and develop a STU3 compatible FHIR server.	1,500	3,500	.....	This is a one-time cost for health IT systems to align with the FHIR STU3 data model and develop a STU3 compatible FHIR server.
Task 2: Enhancements to health IT to upgrade databases and/or other backend infrastructure to appropriately apply security labels to data and/or develop access control capabilities.	Enhancements to health IT to upgrade databases and/or other backend infrastructure to appropriately apply security labels to data and/or develop access control capabilities.	1,500	2,500	.....	This is a *one-time cost* for health IT systems to support data segmentation for discrete data.
Total Labor Hours	.....	3,000	6,000		
Hourly Rate	.....	$100.28			

TABLE 19—COSTS RELATED TO DATA SEGMENTATION FOR PRIVACY USING API—Continued

[2016 Dollars]

Tasks	Details	Lower bound hours	Upper bound hours	Assumptions	Remarks
Cost per Product		$300,840	$601,680		
Total Cost (23 products)		$6,919,320	$13,838,640		

We believe this proposal involving standardized APIs, as well as the voluntary nature of the proposal, would significantly mitigate health IT developer costs. We also expect developers to see a return on their investment in developing and preparing their health IT for these certification criteria given the benefits to interoperable exchange. We welcome comments on this analysis.

We anticipate potential costs for ONC related to this proposal associated with: (1) Developing and maintaining information regarding these new criteria on the ONC website; (2) creating documents related to these new criteria and making those documents 508 compliant; (3) updating, revising, and supporting Certification Companion Guides, test procedures, and test tools; and (4) responding to inquiries concerning these criteria. We estimate an ONC analyst at the GS–13, Step 1 level staff would devote, on average, 200 hours to the above tasks annually. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. Therefore, we estimate the annual costs to be $17,660.

Benefits

We believe leveraging the DS4P standard's ability to allow for both document level and more granular tagging would offer functionality that is more valuable to providers and patients, especially given the complexities of the privacy landscape for multiple care and specialty settings. We also believe this proposal would benefit providers, patients, and ONC because it would support more complete records, contribute to patient safety, and enhance care coordination. We believe this proposal could also reduce burden for providers by enabling an automated option, rather relying on case-by-case manual redaction and subsequent workarounds to transmit redacted documents. We emphasize that health care providers already have processes and workflows to address their existing compliance obligations, which could be made more efficient and cost effective through the use of health IT. We expect these benefits for providers, patients, and ONC to be significant; however, we are unable to quantify these benefits at this time because we do not have adequate information to support quantitative estimates. We welcome comments regarding potential approaches for quantifying these benefits.

(3) Conditions and Maintenance of Certification

3.1 Information Blocking

For a discussion of the costs and benefits of the exceptions to information blocking proposed in this rule, please see section (5) of this RIA.

3.2 Assurances

We are proposing that health IT developers must make certain assurances as Conditions and Maintenance of Certification: (1) Assurances regarding the electronic health information export certification criterion in § 170.315(b)(10) and (2) assurances regarding retaining records and information.

3.2.1 Electronic Health Information Export

We propose, as a Condition of Certification requirement, that a health IT system that produces and electronically manages electronic health information must be certified to the 2015 Edition ''electronic health information export'' certification criterion in § 170.315(b)(10). Further, as a Maintenance of Certification requirement, health IT developers must comply with this proposed Condition of Certification requirement within 24 months of a subsequent final rule's effective date or at the time of certification if the health IT developer never previously certified health IT to the 2015 Edition. As another Maintenance of Certification requirement, we propose that health IT developers must provide all of their customers with the functionality included in § 170.315(b)(10).

For a detailed discussion of the costs and benefits of the assurances regarding the electronic health information export certification criterion in § 170.315(b)(10), please see section 2.2 of this RIA above.

3.2.2 Records and Information Retention

We propose that, as a Maintenance of Certification requirement, a health IT developer must, for a period of 10 years beginning from the date of certification, retain all records and information necessary that demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program. In an effort to reduce administrative burden, we also propose, that in situations where applicable certification criteria are removed from the Code of Federal Regulations before the 10 years have expired, records must only be kept for 3 years from the date of removal for those certification criteria and related Program provisions unless that timeframe would exceed the overall 10-year retention period. This ''3-year from the date of removal'' records retention period also aligns with the records retention requirements for ONC–ACBs and ONC–ATLs under the Program.

Currently, there are no existing regulatory requirements regarding record and information retention by health IT developers. We expect the costs to developers to retain the records and information described above to be mitigated due to the following factors. First, we expect that health IT developers are already keeping the majority of their records and information in an electronic format. Second, we expect that health IT developers already have systems in place for retaining records and information. Last, we expect that some developers may already be retaining records and information for extended periods of time due to existing requirements of other programs, including for those programs their customers participate in. For instance, Medicaid managed care companies are required to keep records for ten years from the effective date of a contract.

We estimate that each health IT developer will, on average, spend two hours each week to comply with our proposed record retention requirement. We expect that a health IT developer's office clerk could complete the record retention responsibilities. According to

the May 2016 BLS occupational employment statistics, the mean hourly wage for an office clerk is $15.87.[180] As noted previously, we have assumed that overhead costs (including benefits) are equal to 100% of pre-tax wages, so the hourly wage including overhead costs is $31.74. Therefore, we estimate the annual cost per developer would, on average, be $3,301 and the total annual cost for all health IT developers (458 health IT developers have products certified to the 2015 Edition that are capable of recording patient health data) would, on average, be $1.5 million. We note that this is a perpetual cost. We welcome comments on these cost estimates.

3.3 Prohibition or Restriction of Communications Costs

Health IT developers would need to notify their customers about the unenforceability of communications and contract provisions that violate this Condition of Certification. Generally, health IT developers should already have mechanisms in place, whether via online postings, email, mail, or phone, for alerting customers to changes in their policies and procedures. Such alerts should be standard practice. However, we have estimated the potential costs for health IT developers to draft the notice and mail the notice as appropriate. We estimate that a health IT developer's office clerk will commit (overall) approximately 40 hours to drafting and mailing notices when necessary. According to the May 2016 BLS occupational employment statistics, the mean hourly wage for an office clerk is $15.87.[181] As noted previously, we have assumed that overhead costs (including benefits) are equal to 100% of pre-tax wages, so the hourly wage including overhead costs is $31.74. Therefore, we estimate the annual cost per developer to be $1,270 and the total cost for all health IT developers (792 health IT developers certified to the 2014 Edition) to be $1 million. We note that this is a one-time cost and would not be perpetual.

We also note that mailing is one option for delivery, along with other means such as email. We do not have information concerning how health IT developers will deliver their notices. We have estimated a total cost for all developers to mail the notices (including postage) to be $80,000. Again, we note that this is a one-time cost. We welcome comments on these cost estimates.

In order to meet the Cures Act requirement that health IT developers do not prohibit or restrict communication regarding health IT, some health IT developers would eventually need to amend their contracts to reflect such a change. Many standard form health IT contracts limit the ability of users to voluntarily discuss problems or report usability and safety concerns that they experience when using their health IT. This type of discussion or reporting is typically prohibited through broad confidentiality, nondisclosure, and intellectual property provisions in the vendor's standard form health IT contract. Some standard form health IT contracts may also include non-disparagement clauses that prohibit customers from making statements that could reflect negatively on the health IT developer. These practices are often referred to colloquially in the industry as ''gag clauses.'' We expect amendments to these clauses to be accomplished in the normal course of business, such as when renegotiating contracts or updating them for HIPAA or other compliance requirements. As such, we do not estimate any direct or indirect costs for health IT developers to amend their contracts to comply with this condition of certification.

Benefits

We expect health care providers to benefit from this proposal. There is growing recognition that these practices of prohibiting or restricting communication do not promote health IT safety or good security hygiene and that health IT contracts should support and facilitate the transparent exchange of information relating to patient care. We are unable to estimate these benefits because we do not have adequate information to determine the prevalence of gag clauses and other such restrictive practices, nor do we have a means to quantify the value to providers of being able to freely communicate and share information. We welcome comments on approaches to quantify these benefits.

3.4 Application Programming Interfaces

For a discussion of the costs and benefits of the new API criterion, please see section 2.3 of this RIA.

3.5 Transparency Requirements for Application Programming Interfaces

We propose as part of the Conditions and Maintenance of Certification that API Technology Suppliers be required to make specific business and technical documentation necessary to interact with the APIs in production freely and publicly accessible. We expect that the API Technology Suppliers would perform the following tasks related to transparency of business and technical documentation and would devote the following number of hours annually to such task: (1) Health Level 7's (HL7®) Fast Healthcare Interoperability Resources (FHIR®) API documentation (the vendor would most likely point to the HL7 FHIR standard for API documentation) (estimated eight hours); (2) patient application registration documentation, which would include a development effort to create a website that manages the application registration activity (estimated 40 hours); (3) publication of the FHIR Endpoint—Base URLs for all centrally managed providers (estimated 40 hours); (4) publication of FHIR Endpoints for provider-managed APIs (estimated 160 hours); and (5) API cost information documentation, which would typically be documented as a tiered rate based on usage or some form of monthly rate (estimated 40 hours).

We believe each of the above tasks would be performed by a ''Software Developer.'' According to the May 2016 BLS occupational employment statistics, the mean hourly wage for software developer is $50.14 [182] As noted previously, we have assumed that overhead costs (including benefits) are equal to 100% of pre-tax wages, so the hourly wage including overhead costs is $100.28. Therefore, we estimate the cost per developer to be $28,881. As noted in section 2.3 of this RIA, we estimate that 459 products from 394 developers will contain the API criterion. Therefore, we estimate the total developer total would be $11.4 million. We note that this is a one-time cost and would not be perpetual.

3.6 Real World Testing

The objective of real world testing is to verify the extent to which deployed health IT products in operational production settings are demonstrating compliance to certification criteria and functioning with the intended use cases for continued maintenance of certification. Real world testing should ensure certified health IT products have the ability to share electronic health information between other systems. Real world testing should assess that the certified health IT is meeting the intended use case(s) of the certification criteria to which it is certified within the workflow, health IT architecture,

[180] *See https://www.bls.gov/oes/2016/may/oes439061.htm.*

[181] *See https://www.bls.gov/oes/2016/may/oes439061.htm.*

[182] *See https://www.bls.gov/oes/2016/may/oes439061.htm.*

and care/practice setting in which the health IT is implemented. We note that we expect real world testing would take about three months of the year to perform.

Costs

This section describes the potential costs of the real world testing requirements in this proposed rule. The costs estimates are based on the following assumptions:

1. *Health IT developers will use the same labor costs.* Table 20 shows the estimated labor costs for a health IT developer to perform real world testing. We recognize that health IT developer costs will vary; however, our estimates in this section assume all developers will incur the costs noted in Table 20.

2. *Proxy needed to project the number of 2015 Edition products impacted by real world testing.* We estimate that 523 products from 429 developers will be impacted by real world testing. We used a proxy to determine developers that would be subject to real world testing There were 681 products and 551 developers with at least one of its 2014 Edition certified products that could perform either (or both) transitions of care and/or send any type of public health data. We then multiplied these numbers by our estimates for certified health IT market consolidation by −22.1% and −23.2% to project number of 2015 developers and products, respectively. We believe this estimate serves as a reasonable proxy for products impacted by real world testing, as these products primarily focus on interoperability.

The tables below describe the various costs to health IT developers to perform real world testing by task.

TABLE 20—ESTIMATED COST TO HEALTH IT DEVELOPERS TO PERFORM REAL WORLD TESTING [a]

[2016 Dollars]

Tasks and labor category	Hours	Rate	Total
Task 1: Design Real World Testing Approach and Submit Plan (per developer)			$33,817
15–1133 Software Developers, Systems Software	80	106.34	8,507.20
15–1143 Computer Network Architects	120	100.24	12,028.80
15–1121 Computer Systems Analysts	80	88.10	7,048.00
15–1199 Computer Occupations, All Other	40	85.46	3,418.40
27–3042 Technical Writers	40	70.36	2,814.40
Task 2: Prepare Staff and Environments (per developer)			14,646
15–1121 Computer Systems Analysts	40	88.10	3,524.00
15–1142 Network and Computer Systems Administrators	40	81.26	3,250.40
15–1152 Computer Network Support Specialists	40	65.16	2,606.40
15–1199 Computer Occupations, All Other	40	85.46	3,418.40
15–1122 Information Security Analysts	20	92.34	1,846.80
Task 3: Perform Testing (per product)			31,577
15–1121 Computer Systems Analysts	80	88.10	7,048.00
15–1133 Software Developers, Systems Software	40	106.34	4,253.60
15–1199 Computer Occupations, All Other	160	85.46	13,673.60
15–1142 Network and Computer Systems Administrators	40	81.26	3,250.40
15–1141 Database Administrators	40	83.78	3,351.20
Task 4: Collect Results and Prepare-Submit Report (per developer)			20,118
15–1199 Computer Occupations, All Other	120	85.46	10,255.20
15–1121 Computer Systems Analysts	80	88.10	7,048.00
27–3042 Technical Writers	40	70.36	2,814.40
Total Labor Hours	1,140		
Other Direct Costs—printing, publishing (per product)			150.00
Total Cost			100,307

[a] Labor rates in this chart are from the BLS. *See https://www.bls.gov/oes/2016/may/oes439061.htm.*

TABLE 21—REAL WORLD TESTING TOTAL ANNUAL COST

[2016 Dollars]

Task	Calculation	Total cost
Task 1	$33,817 × 429 developers	$14,507,407
Task 2	$14,646 × 429 developers	6,283,134
Task 3	$31,577 × 523 products	16,514,666
Task 4	$20,118 × 429 developers	8,630,450
Other Direct Costs	$150 × 429 developers	78,450
Total Cost		46,014,108

Based on the stated assumptions and costs outlined in the above tables, we estimate the total annual cost for real world testing would, on average, be $46 million with an average cost per developer of $107,259.

Benefits

There are a number of benefits that can be attributed to real world testing. Real world testing may impact the effective integration of varied health IT systems, including integration of certified health IT with non-certified and ancillary technologies such as picture archiving and communications systems (PACS) or specialty specific interfaces. Real world testing might also have an effect on the effective implementation of workflows in a clinical setting. In this analysis, we have

calculated the benefits in the following categories:

1. Provider time saved documenting in their EHR due to improved usability.

2. Increased provider satisfaction with their EHR resulting in fewer providers incurring the costs of switching products.

3. Benefits related to reductions in duplicate lab tests, readmissions, ER visits, and adverse drug events due to increased interoperability. We focused on these outcomes for two reasons: (i) Evidence in literature indicate that health information exchange impacts the chosen measures; and (ii) cost of care associated with these measures is high and the impact of health information exchange is likely to result in significant benefits in the form of reduced costs.

The benefit calculations are based on the following assumptions:

1. *Benefits noted in academic literature are assumed accurate and results were not externally validated.* Estimates of the benefits associated with the benefits are based on estimates obtained from the academic literature. Staff reviewed the academic articles for validity, but estimates were not replicated to confirm accuracy.

2. *Hospitals and eligible professionals that participate in the CMS EHR Incentive Program will be impacted.* Estimates are based on the assumption that 439,187 health care providers and/or 4,519 hospitals will be affected by this regulatory action.

3. *Estimates of the impact of real world testing on rates of interoperability (0.1 to 1%) are based on ONC analysis.* To identify the impact of real world testing on interoperability, we used regression analysis. Specifically, we estimated linear probability models that identified impact of 2014 Edition certified EHR on hospitals' interoperability (whether a hospital sends, receives, finds, and integrates summary of care records). Using data from the AHA from years 2014–2015 in the model, we controlled for hospital size, profit status, participation in a health information organization, and state and year fixed effects. The marginal effect of using a 2014 Edition was a five percentage point increase in interoperability. This is an upper bound estimate. For the purpose of this analysis, we assume 0.1% to 1% would be a reasonable range for real world testing to impact interoperability.

4. *Impact of real world testing is also based on the estimated number of providers that switch health IT developers (rate = 5%).* Using CMS Medicare EHR Incentive Program data from years 2013–2016, we estimate the rate of providers (hospitals and eligible professionals) that changed their health IT developer.

5. *Estimates of the rate of eligible professionals (10%) and hospitals (5%) that will be impacted by real world testing are based on ONC complaint data.* Because real world testing is designed to improve usability and interoperability of products, we assume that those eligible professionals and hospitals most likely to be impacted are those who currently use products by health IT developers with complaints.

As noted previously in this analysis, we acknowledge that there might be shared benefits across certain proposals and have taken steps to ensure that the benefits attributed to each proposal are unique to the proposal referenced. Specifically, we used regression analysis to calculate the impact of our real world testing and API proposals on interoperability. We assumed that the real world testing and API proposals would collectively have the same impact on interoperability as use of 2014 Edition certified health IT. Therefore, we estimated linear probability models that identified the impact of 2014 Edition certified health IT on hospitals' interoperability.[183] We controlled for additional factors such as participation in a health information exchange organization, hospital characteristics, and urban/rural status. We found the marginal effect of using 2014 Edition certified health IT was a five percentage point increase in interoperability.

While we acknowledge that there might be shared benefits across proposals, we have taken steps to ensure that the benefits attributed to each proposal is unique to the proposal referenced. We assumed that this marginal effect is true for our proposals and distributed the 5% benefit across our real world testing and API proposals at (.1–1%) to (1–4%) respectively. Moreover, the number of providers impacted is proposal specific. Given data limitations, we believe this approach allows us to estimate the benefits of our proposals without double counting the impact each proposal might have on interoperability.

The first table below shows benefits of real world testing for providers where we monetize the impact of real world testing as total amount saved by reducing provider time spent with the health IT. The impact of real world testing on provider time is expected to represent a larger impact (5%) than the impact of real world testing on health outcomes (1%–4%) and cost. This is primarily because provider behavior is more directly affected by improvements in interoperability.

Benefits of Real World Testing

TABLE 22—BENEFIT OF REAL WORLD TESTING FOR PROVIDERS

[2016 Dollars]

Benefit type	Number affected	Hourly wage	Hours saved (percent) [a b]		Hours per day with EHR	Number of working days in a year	Total benefit [c] (per year)	
			Min	Max			Min	Max
Reduction in provider time spent in health IT by improving usability and interoperability.	43,919 providers or 10% [d] (based on complaint data).	95	1	5	[e] 6	260	$65M	$325M
Administrative time spent in health IT by improving billing, patient matching, product integration.	Using a rule of 0.75 administrative staff per provider,[f] 32,939 personnel.	14.52	1	5	[e] 6	260	7M	37M

[183] American Hospital Association Health IT Supplement Survey, *http://www.ahadata.com/aha-healthcare-database/.*

TABLE 22—BENEFIT OF REAL WORLD TESTING FOR PROVIDERS—Continued

[2016 Dollars]

Benefit type	Number affected	Hourly wage	Hours saved (percent) [a b]		Hours per day with EHR	Number of working days in a year	Total benefit [c] (per year)	
			Min	Max			Min	Max
Number of providers switching health IT [g].	Number 2,195; Cost of Switching Min = $15,000, Max = $70,000.	.....	.....	.....	.....	.....	33M	154M
Total Benefit	.....	.....	.....	.....	.....	.....	105M	516M

[a] Julia Adler-Milstein and Robert S. Huckman, *The Impact of Electronic Health Record Use on Physician Productivity,* Am J Manag Care (Nov. 19, 2013).

[b] Amusan, Tongen, Speedie, and Mellin, *A time-motion study to evaluate the impact of EMR and CPOE implementation on physician efficiency,* J. Healthcare Inf. Manag. (Fall 2008), at 31–7.

[c] Total benefits for the provider and administrative time spent in health IT by improving usability and interoperability. Total benefits from switching EHR vendor is a product of number providers switching and cost of EHR.

[d] The estimate is based on the number of providers that currently possess products with complaints. This is identified by flagging health IT developers and products about whom/which complaints are logged on ONC's database. These health IT developers are then matched to physicians using the Meaningful Use database.

[e] Christine Sinsky et al., *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties*, Ann Intern Med. (Dec. 6, 2016), at 753–60.

[f] Physician Practice, *Calculating the Right Number of Staff for Your Medical Practice, available at http://www.physicianspractice.com/blog/calculating-right-number-staff-your-medical-practice.*

[g] This estimate was obtained from Meaningful Use data from years 2013–2016. "Switching" is defined as an annual change in all health IT developers by providers/hospitals.

TABLE 23—BENEFIT OF REAL WORLD TESTING FOR PATIENTS AND PAYERS

[2016 Dollars]

Benefit type	Population affected	Overall interop impact (marginal effect)	Impact of real world testing		Total cost	Percent of total cost impacted	Total benefit [a] (per year)	
			Min	Max			Min	Max
Duplicate testing ...	35,607 providers ..	[b] 0.09	0.001	0.01	200 Billion [c]	10	$18M	$180M
Avoidable hospitalizations and readmissions.	5% of hospitals (n = 226).	[b] 0.09	0.001	0.01	$41B [d]	5	0.2M	1.8M
ER visits	5% of visits affected.	[b] 0.03	0.001	0.01	Cost per ER visit $1,233, 131M visits [e].	5	2M	2.4M
Adverse drug events.	5% of events affected.	[f] 0.22	0.001	0.01	$30 billion [g]	5	0.33M	3.3M
Total Benefit ..	.....	.....	.....	.....	.....	.....	2.6M	25.6M

[a] Total benefit is a product of *total cost, % of total cost impacted, overall impact of interoperability, and impact of real world testing.*

[b] Stephen E. Ross, Tiffany A. Radcliff, William G. Leblanc, L. Miriam Dickinson, Anne M. Libby, and Donald E. Nease Jr., Effects of health information exchange adoption on ambulatory testing rates, J. Am. Med. Inform. Assoc. (2013), at 1137–1142; Bridget A. Stewart, Susan Fernandes, Elizabeth Rodriguez-Huertas, and Michael Landzberg, A preliminary look at duplicate testing associated with lack of electronic health record interoperability for transferred patients, J. of the Am. Med. Informatics Assoc. (2010), at 341–344; Sezgin Ayabakan, Indranil R. Bardhan, Zhiqiang (Eric) Zheng, and Kirk Kirksey Value of health information sharing in reducing healthcare waste: An analysis of duplicate testing across hospitals, MIS Quarterly (Jan. 1, 2017); Eric J. Lammers, Julia Adler-Milstein, and Keith E. Kocher, Does health information exchange reduce redundant imaging? Evidence from emergency departments, Med Care (Mar. 2014), at 227–34.

[c] National Academy of Medicine. (2016), *http://money.cnn.com/2017/05/20/news/economy/medical-tests/index.html.*

[d] Agency for Healthcare Research and Quality (AHRQ) Statistical Brief #199 (Dec. 2015), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb199-Readmissions-Payer-Age.pdf;* AHRQ Statistical Brief #72, Nationwide Frequency and Costs of Potentially Preventable Hospitalizations (Apr. 2009), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb72.pdf.*

[e] National Center for Health Statistics (NCHS) Data Brief No. 252 (June 2016), *https://www.cdc.gov/nchs/data/databriefs/db252.pdf;* Nolan Caldwell, Tanja Srebotnjak, Tiffany Wang, and Renee Hsia, "How Much Will I Get Charged for This?" Patient Charges for Top Ten Diagnoses in the Emergency Department (2013), *https://doi.org/10.1371/journal.pone.0055491.*

[f] M.F. Furukawa, W.D. Spector, M.R. Limcangco, and W.E. Encinosa, *Meaningful use of health information technology and declines in in-hospital adverse drug events,* J. of the Am. Med. Informatics Assoc. (2017).

[g] Janet Sultana, Paola Cutroneo, and Gianluca Trifirò, *Clinical and economic burden of adverse drug reactions* (Dec. 2013).

Based on the stated assumptions and benefits outlined in Table 22 above, we estimate the total annual benefit for real world testing to providers would, on average, range from $105 million to $516 million. Based on the stated assumptions and benefits outlined in Table 23 above, we estimate the total annual benefit for patients and payers would, on average, range from $4.3 million to $25.5 million. Therefore, we estimate the total benefit of real world testing would, on average, range from $109.3 million to $541.5 million. If we assume, based on our cost estimates, the average annual costs to health IT developers would be $46 million and that increased health IT developer costs are passed to customers, then the net benefit to hospitals/providers would range from $63.3 million to $495.5 million.

We recognize that health IT developers may deploy their systems in a number of ways, including cloud-based deployments, and seek comment on whether our cost estimates of real world testing should factor in such methods of system deployment. For example, we request feedback about whether health IT developers would incur reduced real world testing costs through cloud-based deployments as opposed to other deployment methods. We specifically solicit comment on the general ratio of cloud-based to non-cloud-based deployments within the health care ecosystem and specific cost variations in performing real world testing based on the type of deployment. We also request comment on our assumptions about the burden to providers in time spent assisting health IT developers since we encourage health IT developers to come up with ways to perform real world testing that mitigate provider disruption.

3.6.1 Real World Testing Maintenance Requirements

We propose to revise the Principle of Proper Conduct in § 170.523(m) to require ONC–ACBs to collect, no less than quarterly, all updates successfully made to standards in certified health IT pursuant to the developers having opted to avail themselves of the Standards Version Advancement Process flexibility under the real world testing Condition of Certification. Under § 170.523(p), ONC–ACBs will be responsible for: (1) Reviewing and confirming that applicable health IT developers submit real world testing plans in accordance with § 170.405(b)(1); (2) reviewing and confirming that applicable health IT developers submit real world testing results in accordance with § 170.405(b)(2); and (3) submitting real world testing plans by December 15 and results by April 1 of each calendar year to ONC for public availability. In addition, under § 170.523(t), ONC–ACBs will be required to: (1) Maintain a record of the date of issuance and the content of developers' notices; and (2) timely post content of each notice on the CHPL.

Using the information from the ''Real World Testing'' section of this RIA, we estimate that 429 developers will be impacted by real world testing. We estimate that, on average, it will take an ONC–ACB employee at the GS–13, Step 1 level approximately 30 minutes to collect all updates made to standards in Health IT Modules in accordance with § 170.523(m). The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. Since the collection must occur no less than quarterly, we assume it occurs, on average, four times per year. Therefore, we estimate the annual cost to ONC–ACBs to comply with the collection requirements under § 170.523(m) to be $139,867.

We estimate that, on average, it will take an ONC–ACB employee at the GS–13, Step 1 level approximately 1 hour to review and confirm that applicable health IT developers submit real world testing plans in accordance with § 170.405(b)(1). We estimate that, on average, it will take an ONC–ACB employee at the GS–13, Step 1 level approximately 30 minutes to review and confirm that applicable health IT developers submit real world testing results in accordance with § 170.405(b)(2). We estimate that, on average, it will take an ONC–ACB employee at the GS–13, Step 1 level approximately 30 minutes to submit real world testing plans and results to ONC for public availability. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. Therefore, we estimate the annual cost to ONC–ACBs to comply with the submission and reporting requirements under §§ 170.523(m) and 170.550(l) to be $143,891.

Throughout the RIA we have used 830 products as our 2015 Edition Projection. We came up with this projection by multiplying a −23.2% market consolidation rate from the total number of products certified to 2014 Edition. This assumption was based on the market consolidation rate observed between the 2011 and 2014 Editions. We have estimated the number of 2015 Edition products that will certify each criteria included in the real world testing Condition of Certification. We assume that there will be a cost associated with a notice for each certified criteria (even if an individual product were to update the same standard across multiple criteria that use that standard). This estimation was calculated by multiplying the current percent of 2015 Edition products that certify a criteria by the estimated number of total 2015 Edition products (830).

We assume that the amount of time for an ONC–ACB staff person to (1) maintain a record of the date of issuance and the content of developers' notices; and (2) to timely post content of each notice on the CHPL can be anywhere from 30 minutes to 1 hour.

The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. This was the hourly rate we used for the RIA, so it's consistent with prior calculations. This wage is used to determine the ONC–ACB time cost to complete this requirement under § 170.523(t). Our minimum estimate for the amount of time to comply is 30 minutes per notice. If 25% of certified products update any of the applicable standards, we estimate it will cost $58,807. If all products update any of the applicable standards, we estimate it will cost $235,231. Our maximum estimate for the amount of time to comply is 1 hour per notice. If 25% of certified products update any of the applicable standards, we estimate it will cost $117,615. If all products update any of the applicable standards, we estimate it will cost $470,462. Our lower bound estimate for the cost of this requirement is $58,807. Our upper bound estimate for the cost of this requirement is $470,462.

3.8 Attestations

The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, provide to the Secretary an attestation to all the Conditions and Maintenance of Certification specified in the Cures Act, except for the ''EHR reporting program'' Condition of Certification. It also requires that a health IT developer attest to ensuring that its health IT allows for health information to be exchanged, accessed, and used in the manner described by the API Condition of Certification. We propose to implement the Cures Act ''attestations'' Condition of Certification in § 170.406 by requiring health IT developers to attest to the aforementioned conditions. For the purposes of estimating the potential burden of these attestations on health IT developers, ONC–ACBs, and ONC, we are estimating that all health IT developers under the Program will submit an attestation biannually. As noted previously in this RIA, there are 792 health IT developers certified to the 2014 Edition.

We estimate it will take a health IT developer employee approximately one hour on average to prepare and submit each attestation to the ONC–ACB. According to the May 2016 BLS occupational employment statistics, the mean hourly wage for a software developer is $50.14 [184] Therefore, we estimate the annual cost including overhead costs to be $79,422.

We propose that attestations would be submitted to ONC–ACBs on behalf of ONC and the Secretary. We assume there will be three ONC–ACBs as this is the current number of ONC–ACBs, and we also assume an equal distribution in responsibilities among ONC–ACBs. ONC–ACBs would have two responsibilities related to attestations. One responsibility we propose in § 170.523(q) is that an ONC–ACB must review and submit the health IT developers' attestations to ONC. We estimate it will take an ONC–ACB employee at the GS–13, Step 1 level approximately 30 minutes on average to review and submit each attestation to ONC. The other responsibility we propose in § 170.550(l) is that before issuing a certification, an ONC–ACB would need to ensure that the health IT developer of the Health IT Module has met its responsibilities related to the Conditions and Maintenance of Certification requirements as solely evidenced by its attestation. We estimate it will take an ONC–ACB

[184] *See https://www.bls.gov/oes/2016/may/oes439061.htm.*

employee at the GS–13, Step 1 level approximately one hour on average to complete this task. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. Therefore, we estimate the annual cost to ONC–ACBs to be $209,801.

We propose that ONC would make the attestations publicly available on the CHPL once they are submitted by the ONC–ACBs. ONC posts information regularly to the CHPL and we estimate the added costs to post the attestation will be de minimis. We welcome comments if stakeholders believe more or less networks should be included in our estimate.

(4) Oversight for the Conditions and Maintenance of Certification

ONC's processes for overseeing the Conditions and Maintenance of Certification will, for the most part, mirror ONC's processes for direct review of non-conformities in certified health IT as described in current § 170.580. We have proposed that ONC may directly review a health IT developer's actions to determine whether they conform to the Conditions and Maintenance of Certification requirements proposed in this proposed rule. The estimated costs and benefits for such oversight and review are detailed below.

Costs

We estimated the potential monetary costs of our proposal to allow ONC to directly review a health IT developer's actions to determine whether the actions conform to the requirements of the Program as follows: (1) Costs for health IT developers to correct non-conforming actions identified by ONC; (2) costs for health IT developers and ONC related to ONC review and inquiry into non-conforming actions by the health IT developer; and (3) costs for ONC–ACBs related to the new proposed reporting requirement in the Principles of Proper Conduct in § 170.523(s).

Costs for Health IT Developers To Correct Non-Conforming Actions Identified by ONC

We do not believe health IT developers face additional direct costs for the proposed ONC direct review of health IT developer actions (*see* cost estimates for the Conditions and Maintenance of Certification requirements). However, we acknowledge that this proposed rule may eventually require health IT developers to correct certain actions or non-conformities with their health IT that do not conform to the Conditions and Maintenance of Certification.

If ONC identifies a non-conforming action by a health IT developer, the costs incurred by the health IT developer to bring its actions into conformance would be determined on a case-by-case basis. Factors that would be considered include, but are not limited to: (1) The extent of customers and/or business affected; (2) how pervasive the action(s) is across the health IT developer's business; (3) the period of time that the health IT developer was taking the action(s) in question; and (4) the corrective action required to resolve the issue. We are unable to reliably estimate these costs as we do not have cost estimates for a comparable situation. We request comment on existing relevant data and methods we could use to estimate these costs.

Costs for Health IT Developers and ONC Related to ONC Review and Inquiry Into Health IT Developer Actions

In order to calculate the potential costs to health IT developers and ONC related to ONC review and inquiry into health IT developer actions, we have created the following categories for potential costs: (1) ONC review and inquiry prior to the issuance of a notice of non-conformity; (2) ONC review and inquiry following the issuance of a notice of non-conformity and the health IT developer does not contest ONC's findings (*i.e.,* no appeal); and (3) ONC review and inquiry following the issuance of a notice of non-conformity and the health IT developer contests ONC's findings (*i.e.,* appeal).

ONC Review and Inquiry Prior to the Issuance of a Notice of Non-Conformity

We anticipate that ONC will receive, on average, between 100 and 200 complaints per year concerning the Conditions and Maintenance of Certification that will warrant review and inquiry by ONC. We estimate that such initial review and inquiry by ONC would require, on average, two to three analysts at the GS–13 level working one to two hours each per complaint. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. Therefore, we estimate each review and inquiry would cost ONC, on average, between $177 and $529. We estimate the total annual cost to ONC would, on average, range from $17,700 and $105,800. This range takes into account both the low end of reviews that are resolved quickly and the high end in which staff would need to discuss issues with ONC leadership or in some cases, HHS senior leadership including the Office of General Counsel. We have not estimated health IT developer costs associated with ONC review prior to the issuance of a notice of non-conformity because, in most cases, health IT developers are not required to take action prior to the notice of non-conformity.

ONC Review and Inquiry Following the Issuance of a Notice of Non-Conformity and the Health IT Developer Does Not Contest ONC's Findings

This category would capture cases that require review and inquiry following ONC's issuance of a notice of non-conformity, but that would not proceed to the appeals process. Examples of such situations would include, but not be limited to: (1) A health IT developer violates a Condition of Certification and does not contest ONC's finding that it is in violation of the Condition of Certification; or (2) a health IT developer fails to meet a deadline, such as for its corrective action plan (CAP). We estimate that ONC will, on average, conduct between 12 and 18 of these reviews annually.

We estimate that a health IT developer may commit, on average and depending on complexity, between 10 and 40 hours of staff time per case to provide ONC with all requested records and documentation that ONC would use to review and conduct an inquiry into health IT developer actions, and, when necessary, make a certification ban and/or termination determination. We assumed that the work would be performed by a ''Computer Systems Analyst.'' According to the May 2016 BLS occupational employment statistics, the mean hourly wage for computer systems analyst is $44.05.[185] As noted previously, we have assumed that overhead costs (including benefits) are equal to 100% of pre-tax wages, so the hourly wage including overhead costs would be $88.10. Therefore, we estimate the average annual cost for health IT developers would range from $10,572 to $63,432. We note that some health IT developers' costs are expected to be less and some health IT developers' costs are expected to be more than this estimated cost range. Further, we note that these costs would be perpetual.

We estimate that ONC may commit, on average and depending on complexity, between 8 and 80 hours of staff time to complete a review and inquiry into health IT developer actions. We assume that the expertise of a GS–15, Step 1 federal employee(s) would be

[185] *https://www.bls.gov/oes/2016/may/oes439061.htm.*

necessary. The hourly wage with benefits for a GS–15, Step 1 employee located in Washington, DC is approximately $122.74. Therefore, based on the estimate of between 12 and 18 cases each year, we estimate ONC's annual costs would on, average range, from $11,783 to $176,745. We note that some reviews and inquiries may cost less and some may cost more than this estimated cost range. Further, we note that these costs would be perpetual.

We welcome comments on our estimated costs and any comparable processes and costs that we could use to improve our cost estimates.

ONC Review and Inquiry Following the Issuance of a Notice of Non-Conformity and the Health IT Developer Contests ONC's Findings

As discussed in section VII.C of this preamble, we propose to permit a health IT developer to appeal an ONC determination to issue a certification ban and/or terminate a certification under § 170.581(a)(2)(iii). This category of cost calculations captures cases that require review and inquiry following ONC's issuance of a notice of non-conformity and where the health IT developer contests ONC's finding and files an appeal. We estimate that ONC will, on average, conduct between three and five of these reviews annually.

We estimate that a ''Computer Systems Analyst'' for the health IT developer may commit, on average and depending on complexity, between 20 and 80 hours to provide the required information to appeal a certification ban and/or termination under § 170.581(a)(2)(iii) and respond to any requests from the hearing officer. According to the May 2016 BLS occupational employment statistics, the mean hourly wage for a computer systems analyst is $44.05.[186] Assuming that overhead costs (including benefits) are equal to 100% of pre-tax wages, the hourly wage including overhead costs is $88.10. Therefore, we estimate the annual cost, including overhead costs, for a health IT developer to appeal a certification ban and/or termination under § 170.581(a)(2)(iii) would, on average, range from $5,286 to $35,240. We note that some health IT developers' costs are expected to be less and some health IT developers' costs are expected to be more than this estimated cost range. Further, we note that these costs would be perpetual.

We estimate that ONC would commit, on average and depending on complexity, between 40 and 160 hours of staff time to conduct each appeal. This would include the time to represent ONC in the appeal and support the costs for the hearing officer. We assume that the expertise of a GS–15, Step 1 federal employee(s) would be necessary. The hourly wage with benefits for a GS–15, Step 1 employee located in Washington, DC is approximately $122.74. Therefore, based on the estimate on between three and five cases each year, we estimate the cost for ONC to conduct an appeal would, on average, range from $14,729 to $98,192. We note that some appeals may cost less and some may cost more than this estimated cost range. Further, we note that these costs would be perpetual.

Based on the above estimates, we estimate the total annual costs for health IT developers related to ONC review and inquiry into health IT developer actions would, on average, range from $15,858 to $98,672. We estimate the total annual costs for ONC related to ONC review and inquiry into health IT developer actions would, on average, range from $44,212 to $380,737.

We welcome comments on our estimated costs and any comparable processes and costs that we could use to improve our cost estimates.

Costs for ONC–ACBs

We also note that ONC–ACBs could realize costs associated with the new proposed reporting requirement in the Principles of Proper Conduct in § 170.523(s) that they report, at a minimum, on a weekly basis to the National Coordinator any circumstances that could trigger ONC direct review per § 170.580(a)(2). We estimate that, on average, it will take an ONC–ACB employee at the GS–13, Step 1 level approximately 30 minutes to prepare the report. The hourly wage with benefits for a GS–13, Step 1 employee located in Washington, DC is approximately $88.30. Since the collection must occur no less than weekly, we will assume it occurs, on average, 52 times per year. Therefore, given that there are currently three ONC–ACBs, we estimate the annual cost to ONC–ACBs to comply with the reporting requirement under § 170.523(s) would, on average, be $6,889.

Benefits

This proposed rule's provisions for ONC direct review of the Conditions and Maintenance of Certification requirements would promote health IT developers' accountability for their actions and ensure that health IT developers' actions conform with the requirements of the Cures Act and Conditions and Maintenance of Certification requirements in §§ 170.400–406. Specifically, ONC's direct review of health IT developer actions will facilitate ONC's ability to require comprehensive corrective action by health IT developers to address non-conforming actions determined by ONC. If ONC ultimately implements a certification ban and/or terminates a certification(s), such action will serve to protect the integrity of the Program and users of health IT. While we do not have available means to quantify the benefits of ONC direct review of health IT developer actions, we note that ONC direct review supports and enables the National Coordinator to fulfill his responsibilities under the HITECH Act and Cures Act, instills public confidence in the Program, and protects public health and safety.

(5) Information Blocking

Costs

We expect ONC to incur an annual cost for issuing guidance related to the information blocking ''reasonable and necessary'' exceptions. We assume that the guidance would be provided by ONC staff with the expertise of a GS–15, Step 1 federal employee(s). The hourly wage with benefits for a GS–15, Step 1 employee located in Washington, DC is approximately $122.74. We estimate it would take ONC staff between 200 and 400 hours to develop the guidance. Therefore, we estimate the annual cost to ONC would, on average, range from $98,192 to $196,384.

Benefits

Information blocking not only interferes with effective health information exchange, but also negatively impacts many important aspects of health and health care. To make informed health care decisions, providers and individuals must have timely access to information in a form that is usable. When health information is unavailable, decisions can be impaired—and so too the safety, quality, and effectiveness of care provided to patients. Information blocking impedes progress towards reforming health care delivery and payment because sharing information seamlessly across the care continuum is fundamental to moving to a person-centered, high-performing health care system. Information blocking can undermine consumers' confidence in their health care providers by preventing individuals from accessing their health information and using it to make informed decisions

[186] *See https://www.bls.gov/oes/2016/may/oes439061.htm. https://www.bls.gov/oes/2016/may/oes439061.htm.*

about their health and health care. Information blocking also prevents advances in biomedical and public health research, which require the ability to analyze information from many sources in order to identify public health risks, develop new treatments and cures, and enable precision medicine.

In addition, information blocking is a practice that is profoundly anti-consumer and anti-competition. Information blocking can be used to increase revenue, escalate prices, and prevent market competition both for current and future competitors and for new services. For instance, a study released in 2017 about the prevalence of information blocking and how to address it assessed the perceived motivations for information blocking. The study found that respondents perceived that information-blocking practices by health IT developers were often motivated by a desire to maximize short-term revenue and to increase the likelihood that providers will select their health IT instead of a competitor's health IT. Among hospitals and health systems, the most frequent perceived motivation was also related to improving revenue, namely to strengthen their competitive position in the market, followed by accommodating more important internal priorities than health information exchange.[187]

According to leaders of health information exchange efforts, information blocking is relatively widespread.[188] Half of leaders of health information exchange efforts (n = 60) nationwide reported that they routinely encountered information blocking by health IT developers. The top three types of information blocking practices they encountered on a routine basis included:

- Deployment of products with limited interoperability (49%);
- High fees for health information exchange unrelated to cost (47%); and
- Making third-party access to standardized data difficult (42%).

Many hospitals have experienced the negative impacts of health IT developer information blocking practices. In 2015, almost half of hospitals (46%) nationwide reported difficulty exchanging data with providers whose health IT system differed from theirs and one-quarter of hospitals reported paying additional costs to exchange electronic health information with providers outside their hospital system.[189] There is also emerging evidence related to the negative impacts of information blocking at the market level on hospitals' health information exchange activity.[190] Health information exchange activity among hospitals who are using a dominant health IT developer within a given hospital referral region was found to be significantly higher compared to those that are using a non-dominant health IT developer, particularly in more competitive markets where dominant health IT developers had a smaller share of the market. As information blocking diminishes and information blocking becomes less prevalent, such gaps in rates of exchange and barriers to exchange of health information should diminish. Considering the above motivations for and consequences of information blocking, we believe health care providers and patients will benefit greatly from compliance with the information blocking definition. Our proposal would promote the free flow of electronic health information when and where it is needed.

We have also included provisions in this proposed rule that would establish exceptions to the definition of information blocking, which we estimate will generate significant net benefits. As noted above, section 3022 of the PHSA defines information blocking broadly section 3022(a)(3) instructs authorizes the Secretary to identify reasonable and necessary activities that would be considered establish exceptions to the definition of information blocking. In this rule, we propose to establish several exceptions. The exceptions, if finalized, would create clear guidelines for industry regarding pro-competitive and other beneficial activities and would enable stakeholders to determine more easily and with greater certainty whether their activities are excepted from the information blocking definition. The additional clarity provided by the exceptions would make it easier for these regulated entities to comply with the statute—resulting in reduced compliance costs—and would result in increased predictability, which would allow regulated entities to more effectively plan and invest resources in developing and using interoperable technologies and services to improve health care efficiency and value. Overall, the proposed exceptions are accommodating to legitimate industry practices for health IT developers, hospitals, and health care providers and, we believe, would ease the burden and compliance costs for these parties.

Due to limited data and research available, we have only estimated the benefits of our information blocking proposals for payers, specifically patients and insurers. In order to quantify the magnitude of information blocking and the benefits of restricting information blocking, we estimated the following expression, which gives us the imposed cost of information blocking for each health outcome: [% providers that engage in cross-vendor exchange] × [marginal effect (ME) of information blocking] × [ME effect of interoperability] × [total cost of health outcome].

We extracted the ''ME effect of interoperability'' and ''cost of health outcomes'' from academic literature (*see* citations in Table 24). We used a proxy of the ''percent of providers engaged in cross-vendor exchange'' with the ''percent of hospitals engaged in cross-vendor referral of patients outside their system'' (82% in 2015).

We estimated the ''ME of information blocking'' through the following research design. We looked at hospitals that switched vendors and examined their referral patterns before and after the switch. If hospitals that switched vendors also had to change their referral patterns, this could be evidence of information blocking. To operationalize this experiment, we estimated the following equation:

$$Y = b * S + r + h + e.$$

In this equation, the variables are as follows:

- Y = Percent of referrals to providers using a vendor to which the hospital switched
- b = Estimate of interest, which reflects the change in referral to the vendors after the switch relative to hospitals that did not switch. After controlling for hospital and year fixed, this is essentially an interaction effect of the year with the switch.
- S = Indicator for whether hospital switched vendor
- r = Year
- h = Hospital fixed effects
- e = Error term (every regression has an error term)

We used CMS referral data and linked it with Healthcare Information and Management Systems Society (HIMSS) and AHA data for information on hospitals' vendors and other characteristics. Our estimate for ''b'' is 0.4 percentage points, meaning if a

[187] Julia Adler-Milstein and Eric Pfeifer, *Information Blocking: Is It Occurring And What Policy Strategies Can Address It?,* 95 Milbank Quarterly 117 (Mar. 2017) at 124–5, *available at http://onlinelibrary.wiley.com/doi/10.1111/1468-0009.12247/full.*

[188] *Id.*

[189] Vaishali Patel, JaWanna Henry, Yuriy Pylypchuk, and Talisha Searcy, Interoperability among U.S. Non-federal Acute Care Hospitals in 2015, ONC Data Brief, No.36 (May 2016).

[190] Jordan Everson and Julia Adler-Milstein, *Engagement In Hospital Health Information Exchange Is Associated With Vendor Marketplace Dominance,* Health Affairs. 35, No. 7 (2016), at 1286–93.

hospital switches to vendor X, the referrals to hospitals with that vendor increases by a rate of 0.4 percentage points. This number we interpret as a proxy for the extent to which difficulties in cross vendor exchange hinder patient care. However, our finding does not imply that difficulties in cross vendor exchange can be entirely attributed to information blocking. One source of difficulties could be explained by technological challenges where inherent software differences among vendors hinder cross vendor exchange. An additional reason for this result could be attributed to contractual agreements where vendors may incentivize their clients to exchange with other clients having the same vendor. Nevertheless, to keep our estimates conservative, we reduced our estimates by a factor of five. Hence, we use 0.08 percentage points as the ''ME of information blocking.''

Our estimates are detailed in the table below.

TABLE 24—BENEFITS OF PROHIBITING AND/OR DETERRING INFORMATION BLOCKING

[2016 Dollars]

Benefit type	Percent of total cost impacted	Total cost	Overall interop impact (marginal effect)	Percent of providers susceptible to information blocking	Marginal effect of information blocking	Benefit [a]
Duplicate testing	100	200 Billion [b]	[c] 0.09	82	0.08	$1.1B
Avoidable hospitalizations and readmissions.	100	$41B [d]	0.09	82	0.08	242M
ER visits	100	Cost per ER visit $1,233, 131M visits [e].	0.03	82	0.08	317M
Adverse drug events	100	$30 billion [f]	0.22	82	0.08	86M
Total benefit per year						1.8B

[a] Total benefit is a product of *% of total cost impacted, total cost, overall interop impact, percent of providers susceptible to information blocking, and marginal effect of information blocking.*

[b] National Academy of Medicine (2016), *http://money.cnn.com/2017/05/20/news/economy/medical-tests/index.html.*

[c] Stephen E. Ross, Tiffany A. Radcliff, William G. Leblanc, L. Miriam Dickinson, Anne M. Libby, and Donald E. Nease Jr., *Effects of health information exchange adoption on ambulatory testing rates,* J. Am. Med. Inform. Assoc. (2013), at 1137–1142; Bridget A. Stewart, Susan Fernandes, Elizabeth Rodriguez-Huertas, and Michael Landzberg, *A preliminary look at duplicate testing associated with lack of electronic health record interoperability for transferred patients,* J. of the Am. Med. Informatics Assoc. (2010), at 341–344; Sezgin Ayabakan, Indranil R. Bardhan, Zhiqiang (Eric) Zheng, and Kirk Kirksey *Value of health information sharing in reducing healthcare waste: An analysis of duplicate testing across hospitals,* MIS Quarterly (Jan. 1, 2017); Eric J. Lammers, Julia Adler-Milstein, and Keith E. Kocher, *Does health information exchange reduce redundant imaging? Evidence from emergency departments,* Med Care (Mar. 2014), at 227–34.

[d] Agency for Healthcare Research and Quality (AHRQ) Statistical Brief #199 (Dec. 2015), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb199-Readmissions-Payer-Age.pdf;* AHRQ Statistical Brief #72, Nationwide Frequency and Costs of Potentially Preventable Hospitalizations (Apr. 2009), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb72.pdf.*

[e] National Center for Health Statistics (NCHS) Data Brief No. 252 (June 2016), *https://www.cdc.gov/nchs/data/databriefs/db252.pdf;* Nolan Caldwell, Tanja Srebotnjak, Tiffany Wang, and Renee Hsia, ''How Much Will I Get Charged for This?'' Patient Charges for Top Ten Diagnoses in the Emergency Department (2013), *https://doi.org/10.1371/journal.pone.0055491.*

[f] Janet Sultana, Paola Cutroneo, and Gianluca Trifirò, *Clinical and economic burden of adverse drug reactions.*

We request comment on our approach to estimating these benefits, as well as the benefit estimates in the table above.

(6) Total Annual Cost Estimate

We estimate that the total annual cost for this proposed rule for the first year after it is finalized (including one-time costs), based on the cost estimates outlined above and throughout this RIA, would, on average, range from $365 million to $919 million with an average annual cost of $642 million. We estimate that the total perpetual cost for this proposed rule (starting in year two), based on the cost estimates outlined above, would, on average, range from $228 million to $452 million with an average annual cost of $340 million. We also include estimates based on the stakeholder group affected. We estimate the total costs to health IT developers to be between $373 million and $933 million (including one-time and perpetual costs) with $569,000 in cost savings. We estimate the total costs to ONC–ACBs to be between $213,000 and $311,000. We estimate the government (ONC) costs to be between $44,800 and $269,000 while saving $4,500. In addition, to the above mentioned cost savings that are attributable to specific stakeholder groups, we estimate to an additional cost savings of $6.8 million to $13.7 million to all stakeholders affected by this proposal. We are unable to attribute these amounts to specific stakeholder groups.

(7) Total Annual Benefit Estimate

We estimate the total annual benefit for this proposed rule, based on the benefit estimates outlined above, would range from $3.08 billion to $9.15 billion with an average annual benefit of $6.1 billion. We attribute between $756 million and $3.8 billion in benefits to hospitals and clinicians. We attribute between $2.1 billion and $2.9 billion to payers and patients. Our estimates include benefits attributed to the whole health care system, not just to the stakeholders mentioned above.

(8) Total Annual Net Benefit

We estimate the total annual net benefit for this proposed rule for the first year after it is finalized (including one-time costs), based on the estimates outlined above, would range from $2.7 billion to $8.2 billion with an average net benefit of $5.5 billion. We estimate the total perpetual annual net benefit for this proposed rule (starting in year two), based on the estimates outlined above, would range from $2.9 billion to $8.7 billion with an average net benefit of $5.8 billion.

b. Accounting Statement and Table

When a rule is considered an economically significant rule under Executive Order 12866, we are required to develop an accounting statement indicating the classification of the expenditures associated with the provisions of the proposed rule. Monetary annual benefits are presented as discounted flows using 3% and 7% factors in Table 25 below. We are not able to explicitly define the universe of

all costs, but have provided an average of likely costs of this proposed rule as well as a high and low range of likely costs. This proposed rule requires no federal annual monetized transfers.

TABLE 25—E.O. 12866 SUMMARY TABLE

[In $ millions, 2016 time period]

	Primary (3%)	Lower bound (3%)	Upper bound (3%)	Primary (7%)	Lower bound (7%)	Upper bound (7%)
Present Value of Quantified Costs	1,557	1,043	2,070	1,394	934	1,853
Non-quantified Costs	Text					
Present Value of Quantified Benefits	27,998	14,100	41,896	25,067	12,624	37,509
Non-quantified Benefits	Text					
Present Value of Net Benefits	2,456	1,129	37,620	2,190	1,011	33,681
Annualized Quantified Costs	330	355	433	318	365	422
Non-quantified Costs	Text					
Annualized Quantified Benefits	5,935	2,989	8,881	5,714	2,878	8,550
Non-quantified Benefits	Text					
Annualized Net Quantified Benefits	5,184	2,304	7,975	4,991	2,838	8,128

TABLE 26—E.O. 12866 SUMMARY TABLE NON-DISCOUNTED FLOWS

[2016 Dollars]

	Year 1	Year 2	Year 3	Year 4	Year 5
Costs	$641,853,087	$339,870,993	$339,870,993	$339,870,993	$339,870,993
Net Benefits	5,471,742,914	5,773,725,008	5,773,725,008	5,773,725,008	5,773,725,008
	Year 6	Year 7	Year 8	Year 9	Year 10
Costs	$339,870,993	$339,870,993	$339,870,993	$339,870,993	$339,870,993
Net Benefits	5,773,725,008	5,773,725,008	5,773,725,008	5,773,725,008	5,773,725,008

3. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The Small Business Administration (SBA) establishes the size of small businesses for federal government programs based on average annual receipts or the average employment of a firm.[191] The entities that are likely to be directly affected by the requirements in this proposed rule requirements are health IT developers. We note that the proposed reasonable and necessary activities that do not constitute information blocking provide flexibilities and relief for health IT developers of certified health IT, health information networks, health information exchanges, and health care providers in relation to the information blocking provision of the Cures Act. These proposed reasonable and necessary activities also take into account the potential burden on small entities to meet these ''exceptions'' to information blocking, such as with considering the size and resources of small entities when meeting security requirements to qualify for the ''promoting the security of electronic health information'' exception. We refer readers to section VIII for our information blocking-related proposals and welcome comments on their impacts on small entities.

While health IT developers that pursue certification of their health IT under the Program represent a small segment of the overall information technology industry, we believe that many health IT developers impacted by the requirements proposed in this proposed rule most likely fall under the North American Industry Classification System (NAICS) code 541511 ''Custom Computer Programming Services.'' [192] The SBA size standard associated with this NAICS code is set at $27.5 million annual receipts or less. There is enough data generally available to establish that between 75% and 90% of entities that are categorized under the NAICS code 541511 are under the SBA size standard. We also note that with the exception of aggregate business information available through the U.S. Census Bureau and the SBA related to NAICS code 541511, it appears that many health IT developers that pursue certification of their health IT under the Program are privately held or owned and do not regularly, if at all, make their specific annual receipts publicly available. As a result, it is difficult to locate empirical data related to many of these health IT developers to correlate to the SBA size standard. However, although not perfectly correlated to the size standard for NAICS code 541511, we do have information indicating that over 60% of health IT developers that have had Complete EHRs and/or Health IT Modules certified to the 2011 Edition have less than 51 employees.

We estimate that the proposed requirements in this proposed rule would have effects on health IT developers, some of which may be small entities, that have certified health IT or are likely to pursue certification of their health IT under the Program. We believe, however, that we have proposed the minimum amount of requirements necessary to accomplish our primary policy goal of enhancing interoperability. Further, as discussed in section XIV.B of this RIA above, there are no appropriate regulatory or non-regulatory alternatives that could be developed to lessen the compliance burden associated with this proposed

[191] The SBA references that annual receipts means ''total income'' (or in the case of a sole proprietorship, ''gross income'') plus ''cost of goods sold'' as these terms are defined and reported on Internal Revenue Service tax return forms.

[192] *https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf. https://www.sba.gov/sites/default/files/files/Size_Standards_Table_2017.pdf.*

rule because many of the proposals are derived directly form legislative mandates in the Cures Act. Additionally, we have attempted to offset some of the burden imposed on health IT developers in this proposed rule with cost saving proposals through deregulatory actions (*see* proposed section III).

We do not believe that the proposed requirements of this proposed rule would create a significant impact on a substantial number of small entities, but request comment on whether there are small entities that we have not identified that may be affected in a significant way by this proposed rule. Additionally, the Secretary proposes to certify that this proposed rule would not have a significant impact on a substantial number of small entities.

4. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Nothing in this proposed rule imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has federalism implications. We are not aware of any state laws or regulations that are contradicted or impeded by any of the proposals in this proposed rule. We welcome comments on this assessment.

5. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that imposes unfunded mandates on state, local, and tribal governments or the private sector requiring spending in any one year of $100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately $150 million. While the estimated potential cost effects of this proposed rule reach the statutory threshold, we do not believe this proposed rule imposes unfunded mandates on state, local, and tribal governments or the private sector. We welcome comments on these conclusions.

6. Executive Order 13771 Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' The Department believes that this rule is a significant regulatory action as defined by Executive Order 12866 which imposes costs, and therefore is considered a regulatory action under Executive Order 13771. The Department estimates that this rule generates $275 million in annualized costs at a 7% discount rate, discounted relative to 2016, over a perpetual time horizon.

OMB reviewed this proposed rule.

List of Subjects

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

45 CFR Part 171

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health care provider, Health information exchange, Health information technology, Health information network, Health insurance, Health records, Hospitals, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, is proposed to be amended as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

■ 2. Revise § 170.101 to read as follows:

§ 170.101 Applicability.

The standards, implementation specifications, and certification criteria adopted in this part apply to Health IT Modules and the testing and certification of such Health IT Modules.

■ 3. Amend § 170.102 as follows:

■ a. Remove the definitions of ''2014 Edition Base EHR'', and ''2014 Edition EHR certification criteria'';

■ b. Amend the definition of ''2015 Edition Base EHR'' by revising paragraph (3);

■ c. Add, in alphabetical order, the definitions for ''API Data Provider'', ''API Technology Supplier'', and ''API User'';

■ d. Remove the definitions of ''Common Clinical Data Set'', and ''Complete EHR, 2014 Edition''; and

■ e. Add, in alphabetical order, the definitions for ''Fee'', ''Interoperability'', and ''Interoperability element''.

The revisions and additions read as follows:

§ 170.102 Definitions.

* * * * *

2015 Edition Base EHR * * *

(3) Has been certified to the certification criteria adopted by the Secretary in—

(i) Section 170.315(a)(1), (2), or (3); (5); (9); (14); (b)(1); (c)(1); (g)(7) and (9); and (h)(1) or (2);

(ii) Section 170.315(g)(8) or (10) until [24 months from the final rule's effective date]; and

(iii) Section 170.315(b)(10) and (g)(10) on and after [24 months from the final rule's effective date].

* * * * *

API Data Provider refers to the organization that deploys the API technology created by the ''API Technology Supplier'' and provides access via the API technology to data it produces and electronically manages. In some cases, the API Data Provider may contract with the API Technology Supplier to perform the API deployment service on its behalf. However, in such circumstances, the API Data Provider retains control of what and how information is disclosed and so for the purposes of this definition is considered to be the entity that deploys the API technology.

API Technology Supplier refers to a health IT developer that creates the API technology that is presented for testing and certification to any of the certification criteria adopted or proposed for adoption at § 170.315(g)(7) through (11).

API User refers to persons and entities that use or create software applications that interact with the APIs developed by the ''API Technology Supplier'' and deployed by the ''API Data Provider.'' An API User includes, but is not limited to, third-party software developers, developers of software applications used by API Data Providers, and patients and health care providers that use apps that connect to API technology on their behalf.

* * * * *

Fee is defined as it is in § 171.102 of this subchapter.

* * * * *

Interoperability is, with respect to health information technology, such health information technology that—

(i) Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

(ii) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and

(iii) Does not constitute information blocking as defined in § 171.103 of this subchapter.

Interoperability element is defined as it is in § 171.102 of this subchapter.

* * * * *

§ 170.200 [Amended]

■ 4. Amend § 170.200 by removing the phrase ''Complete EHRs and.''

§ 170.202 [Amended]

■ 5. Amend § 170.202 by removing and reserving paragraph (a)(1).

§ 170.204 [Amended]

■ 6. Amend § 170.204 by removing and reserving paragraphs (b)(1) and (2), and by removing paragraph (c).

■ 7. Amend § 170.205 as follows:

■ a. Remove and reserve paragraphs (a)(1) and (2);

■ b. Add paragraph (a)(4)(i) and add and reserve paragraph (a)(4)(ii);

■ c. Add paragraph (b)(1);

■ d. Remove and reserve paragraphs (d)(2), (d)(3), (e)(3), (h)(1), (i)(1), and (j); and

■ e. Add paragraphs (h)(3) and (k)(3).

The revisions read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

(a) * * *

(4) * * *

(i) *Standard.* HL7 CDA® R2 Implementation Guide: C–CDA Templates for Clinical Notes R1 Companion Guide, Release 1 (incorporated by reference in § 170.299).

(ii) [Reserved]

* * * * *

(b) * * *

(1) *Standard.* National Council for Prescription Drug Programs (NCPDP), Script Standard Implementation Guide, Version 2017071 (incorporated by reference in § 170.299).

* * * * *

(h) * * *

(3) CMS Implementation Guide for Quality Reporting Document Architecture Category I Hospital Quality Reporting Implementation Guide for 2019 (incorporated by reference in § 170.299).

* * * * *

(k) * * *

(3) CMS Implementation Guide for Quality Reporting Document Architecture Category III Eligible Clinicians and Eligible Professionals Programs Implementation Guide for 2019 (incorporated by reference in § 170.299).

* * * * *

§ 170.207 [Amended]

■ 8. Amend § 170.207 by removing and reserving paragraphs (d)(2), (e)(2), (g)(1), (h), and (j).

§ 170.210 [Amended]

■ 9. Amend § 170.210 by removing and reserving paragraphs (a)(1) and (c)(1).

■ 10. Add § 170.213 to read as follows:

§ 170.213 United States Core Data for Interoperability

Standard. United States Core Data for Interoperability (USCDI), Version 1 (v1) (incorporated by reference in § 170.299).

■ 11. Add § 170.215 to read as follows:

§ 170.215 Application Programming Interface Standards.

The Secretary adopts the following application programming interface (API) standards and associated implementation specifications:

(a)(1) *Standard.* HL7 Fast Healthcare Interoperability Resources (FHIR) Draft Standard for Trial Use (DSTU) 2 (v1.0.2–7202) (incorporated by reference in § 170.299).

(2) *Implementation specifications. API Resource Collection in Health (ARCH) Version 1* (incorporated by reference in § 170.299).

(3) *Implementation specifications—FHIR profiles.* Argonaut Data Query Implementation Guide Version 1.0.0 (incorporated by reference in § 170.299).

(4) *Implementation specifications—FHIR server conformance.* Argonaut Data Query Implementation Guide Server (incorporated by reference in § 170.299).

(5) *Implementation specification—Application authorization. HL7* SMART Application Launch Framework Implementation Guide Release 1.0.0, including mandatory support for ''refresh tokens,'' ''Standalone Launch,'' and ''EHR Launch'' requirements (incorporated by reference in § 170.299).

(b) *Application authentication. Standard.* OpenID Connect Core 1.0 incorporating errata set 1 (incorporated by reference in § 170.299).

(c)(1) *Standard.* HL7 Fast Healthcare Interoperability Resources (FHIR) Release 3 Standard for Trial Use (STU) 3 (v3.0.1) (incorporated by reference in § 170.299).

(2) *Implementation specification—FHIR consent resources. HL7* Consent2Share FHIR Consent Profile Design (incorporated by reference in § 170.299).

■ 12. Amend § 170.299 as follows:

■ a. Remove and reserve paragraphs (c)(2), (3), (d)(2), (7), and (8);

■ b. Add paragraphs (e)(4) and (5);

■ c. Remove and reserve paragraphs (f)(3), (6), (7), (10), and (11);

■ d. Add paragraphs (f)(30) through (36);

■ e. Redesignate paragraphs (o) through (r) and (g) through (n) as paragraphs (q) through (t) and (h) through (o), respectively;

■ f. Add new paragraph (g) and paragraph (i)(4);

■ g. Remove and reserve newly redesignated paragraph (k)(1);

■ h. Add paragraph (l)(3);

■ i. Remove and reserve newly redesignated paragraph (m)(3);

■ j. Add paragraphs (n)(5) and (6);

■ k. Add new paragraph (p); and

■ l. Remove and reserve newly redesignated paragraphs (s)(4), and (5).

The additions and revisions read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(e) * * *

(4) CMS Implementation Guide for Quality Reporting Document Architecture Category I Hospital Quality Reporting Implementation Guide for 2019, May 4, 2018, IBR approved for § 170.205(h).

(5) CMS Implementation Guide for Quality Reporting Document Architecture Category III Eligible Clinicians and Eligible Professionals Programs Implementation Guide for 2019, October 8, 2018, IBR approved for § 170.205(k).

(f) * * *

(30) HL7 CDA Release 2 Implementation Guide: C–CDA Templates for Clinical Notes R1 Companion Guide, Release 1, March 2017, IBR approved for § 170.205(a).

(31) HL7 Fast Healthcare Interoperability Resources (FHIR®) Release 2.0, Draft Standard for Trial Use (DSTU) Version 1.0.2–7202, October 24, 2015, IBR approved for § 170.215(a).

(32) HL7 Fast Healthcare Interoperability Resource Specification (FHIR®) Release 3 Standard for Trial Use (STU), Version 3.0.1, February 21, 2017, IBR approved for § 170.215(c).

(33) HL7 Fast Healthcare Interoperability Resources Specification (FHIR®) Release 4, Version 4.0.0,

December 27, 2018, IBR approved for § 170.215.

(34) HL7 Implementation Specification—FHIR Profile: Consent2Share FHIR Consent Profile Design, December 11, 2017, IBR approved for § 170.215(c).

(35) HL7 CDA R2 Implementation Guide: C–CDA Supplemental Templates for Unique Device Identification (UDI) for Implantable Medical Devices, Release 1—US Realm, November 15, 2018, IBR approved for § 170.205.

(36) HL7 SMART Application Launch Framework Implementation Guide Release 1.0.0, November 13, 2018, IBR approved for § 170.215(a).

(g) HL7® FHIR® Foundation. 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677–7777 or *https://www.fhir.org/.*

(1) Argonaut Data Query Implementation Guide. Version 1.0.0, December 23, 2016, IBR approved for § 170.215(a).

(2) Argonaut Data Query Implementation Guide Server, Version 1.0.2, December 15, 2016, IBR approved for § 170.215(a).

* * * * *

(i) * * *

(4) OAuth 2.0 Dynamic Client Registration Protocol (RFC 7591), July 2015, IBR approved for § 170.215.

* * * * *

(l) * * *

(3) National Council for Prescription Drug Programs (NCPDP), Script Standard Implementation Guide, Version 2017071 (Approval Date for ANSI: July 28, 2017), IBR approved for § 170.205(b).

* * * * *

(n) * * *

(5) ONC United States Core Data for Interoperability (USCDI), Version 1 (v1), February 11, 2019, IBR approved for § 170.213; available at *https://www.healthit.gov/USCDI.*

(6) API Resource Collection in Health (ARCH) Version 1, February 1, 2019, IBR approved for § 170.215(a); available at *https://www.healthit.gov/ARCH.*

* * * * *

(p) OpenID Foundation, 2400 Camino Ramon, Suite 375, San Ramon, CA 94583, Telephone +1 925–275–6639, *http://openid.net/.*

(1) OpenID Connect Core 1.0 Incorporating Errata Set 1, November 8, 2014, IBR approved for § 170.215(b).

(2) [Reserved]

* * * * *

§ 170.300 [Amended]

■ 14. Amend § 170.300 in paragraphs (a) and (c) by removing the phrase ''Complete EHRs and''.

§ 170.314 [Removed and Reserved]

■ 15. Remove and reserve § 170.314.

■ 16. Amend § 170.315 as follows:

■ a. Remove and reserve paragraphs (a)(6) through (8), (10); (11); and (13);

■ b. In paragraphs (b)(1)(ii)(A) introductory text, (b)(1)(ii)(A)(2), (3), (b)(1)(ii)(B) and (C), remove the reference ''§ 170.205(a)(3) and § 170.205(a)(4)'' and add in its place the reference ''§ 170.205(a)(3), (a)(4), and (a)(4)(i)'';

■ c. In paragraph (b)(1)(iii) introductory text, remove the reference ''§ 170.205(a)(4)'' and add in its place the reference ''§ 170.205(a)(3), (a)(4), and (a)(4)(i)'';

■ d. Revise paragraph (b)(1)(iii)(A);

■ e. In paragraph (b)(2)(i) and (ii), remove the reference ''§ 170.205(a)(3) and § 170.205(a)(4)'' and add in its place the reference ''§ 170.205(a)(3), (a)(4), and (a)(4)(i)'';

■ f. Remove and reserve paragraphs (b)(4) through (8);

■ g. Revise paragraph (b)(9);

■ h. Add paragraphs (b)(10), (11), (12), (13),

■ i. Revise paragraph (c)(3);

■ j. Add paragraphs (d)(12), and (13);

■ k. Revise paragraph (e)(1)(i)(A)(1);

■ l. In paragraph (e)(1)(i)(B)(1)(ii) and (e)(1)(i)(B)(2) introductory text, remove the reference ''§ 170.205(a)(4)'' and add in its place the reference ''§ 170.205(a)(4) and (a)(4)(i)'';

■ m. Remove and reserve paragraph (e)(1)(ii)(B);

■ n. Remove and reserve paragraph (e)(2);

■ o. Revise paragraphs (f)(5)(iii)(B)(1), (g)(6) introductory text, (g)(6)(i) and (iv);

■ p. Revise paragraphs (g)(1) and (g)(2) by removing ''EHR Incentive Programs'' and adding in its place ''Promoting Interoperability Programs'';

■ q. Revising paragraph (g)(3)(i);

■ r. In paragraphs (g)(6)(ii) and (iii), Remove the reference ''§ 170.205(a)(4)'' and add in its place the reference ''§ 170.205(a)(4) and (a)(4)(i)'';

■ s. Revise paragraph (g)(6)(iv);

■ t. Remove paragraphs (g)(7)(ii)(A)(*3*);

■ u. Revise paragraph (g)(9)(i)(A);

■ v. Remove paragraph (g)(9)(ii)(A)(*3*); and

■ w. Add paragraphs (g)(10) and (g)(11).

The revisions and additions read as follows:

§ 170.315 2015 Edition health IT certification criteria.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(A) The data classes expressed in the standard in § 170.213 and, including as specified for the following data:

(1) Assessment and plan of treatment. In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in § 170.205(a)(4) and (a)(4)(i); or in accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(2) Goals. In accordance with the ''Goals Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(3) Health concerns. In accordance with the ''Health Concerns Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(4) Unique device identifier(s) for a patient's implantable device(s). In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

* * * * *

(4) [Reserved]

(5) [Reserved]

(6) [Reserved]

(7) [Reserved]

(8) [Reserved]

(9) *Care plan.* Enable a user to record, change, access, create, and receive care plan information in accordance with:

(i) The Care Plan document template, including the Health Status Evaluations and Outcomes Section and Interventions Section (V2), in the standard specified in § 170.205(a)(4); and

(ii) The standard in § 170.205(a)(4)(i).

(10) *Electronic health information export.* (i) *Single patient electronic health information export.*

(A) Enable a user to timely create an export file(s) with all of a single patient's electronic health information the health IT produces and electronically manages on that patient.

(B) A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(C) Limit the ability of users who can create such export file(s) in at least one of these two ways:

(1) To a specific set of identified users.

(2) As a system administrative function.

(D) The export file(s) created must be electronic and in a computable format.

(E) The export file(s) format, including its structure and syntax, must be included with the exported file(s).

(ii) *Database export.* Create an export of all the electronic health information the health IT produces and electronically manages.

(A) The export created must be electronic and in a computable format.

(B) The export's format, including its structure and syntax must be included with the export.

(iii) *Documentation.* The export format(s) used to support single patient electronic health information export as specified in paragraph (b)(10)(i) of this section and database export as specified in paragraph (b)(10)(ii) of this section must be made available via a publicly accessible hyperlink.

(11) *Electronic prescribing.* (i) Enable a user to perform all of the following prescription-related electronic transactions in accordance with the standard specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows:

(A) Ask mailbox (GetMessage).

(B) Relay acceptance of transaction (Status).

(C) Error response (Error).

(D) Create new prescriptions (NewRx, NewRxRequest, NewRxResponseDenied).

(E) Change prescriptions (RxChangeRequest, RxChangeResponse).

(F) Renew prescriptions (RxRenewalRequest, RxRenewalResponse).

(G) Resupply (Resupply).

(H) Return receipt (Verify).

(I) Cancel prescriptions (CancelRx, CancelRxResponse).

(J) Receive fill status notifications (RxFill, RxFillIndicatorChange).

(K) Drug administration (DrugAdministration).

(L) Transfer (RxTransferRequest, RxTransferResponse, RxTransferConfirm).

(M) Recertify (Recertification).

(N) Request and receive medication history (RxHistoryRequest, RxHistoryResponse).

(O) Complete risk evaluation and mitigation strategy transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).

(ii) For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements in DRU Segment.

(iii) *Optional.* For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the indication elements in the SIG Segment.

(iv) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (*i.e.,* not cc).

(v) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

(12) *Data segmentation for privacy—send.* Enable a user to create a summary record formatted in accordance with the standard adopted in § 170.205(a)(4) and (a)(4)(i) that is tagged as restricted at the document, section, and entry (data element) level and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).

(13) *Data segmentation for privacy—receive.* Enable a user to:

(i) Receive a summary record that is formatted in accordance with the standard adopted in § 170.205(a)(4) and (a)(4)(i) that is tagged as restricted at the document, section, and entry (data element) level and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1); and

(ii) Preserve privacy markings to ensure fidelity to the tagging based on consent and with respect to sharing and re-disclosure restrictions.

(c) * * *

(3) *Clinical quality measures—report.* Enable a user to electronically create a data file for transmission of clinical quality measurement data in accordance with the implementation specifications specified in § 170.205(h)(3) and (k)(3).

* * * * *

(d) * * *

* * * * *

(12) *Encrypt authentication credentials.* Health IT developers must assess their Health IT Modules' capabilities and make one of the following attestations:

(i) ''Yes.'' Health IT Module encrypts stored authentication credentials in accordance with standards adopted in § 170.210(a)(2).

(ii) ''No.'' Health IT Module does not encrypt stored authentication credentials.

(13) *Multi-factor Authentication.* Health IT developers must assess their Health IT Modules' capabilities and make one of the following attestations:

(i) ''Yes.'' Health IT Module supports authentication through multiple elements the identity of the user with industry recognized standards.

(ii) ''No.'' Health IT Module does not support authentication through multiple elements the identity of the user with industry recognized standards.

(e) * * *

(1) * * *

(i) * * *

(A) * * *

(1) The data classes expressed in the standard in § 170.213 (which should be in their English (*i.e.,* non-coded) representation if they associate with a vocabulary/code set), including as specified for the following data:

(i) Assessment and plan of treatment. In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in § 170.205(a)(4) and (a)(4)(i); or in accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(ii) Goals. In accordance with the ''Goals Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(iii) Health concerns. In accordance with the ''Health Concerns Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(iv) Unique device identifier(s) for a patient's implantable device(s). In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

* * * * *

(ii) * * *

(B) [Reserved]

* * * * *

(f) * * *

(5) * * *

(iii) * * *

(B) * * *

(1) The data classes expressed in the standard in § 170.213.

* * * * *

(g) *Design and performance*—(1) *Automated numerator recording.* For each Promoting Interoperability Programs percentage-based measure, technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

(2) *Automated measure Calculation.* For each Promoting Interoperability Programs percentage-based measure that is supported by a capability included in a technology, record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable measure.

(3) * * *

(i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: Paragraphs (a)(1) through (5), (9), and (14); and (b)(2), (3), and (11).

* * * * *

(6) *Consolidated CDA creation performance.* The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (iv) of

this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially. This certification criterion's scope includes only the data classes expressed in the standard in § 170.213.

(i) *Reference C–CDA match.* Create a data file formatted in accordance with the standard adopted in § 170.205(a)(4) and (a)(4)(i) that matches a gold-standard, reference data file, including as specified for the following data:

(A) Assessment and plan of treatment. In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in § 170.205(a)(4) and (a)(4)(i); or in accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(B) Goals. In accordance with the ''Goals Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(C) Health concerns. In accordance with the ''Health Concerns Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(D) Unique device identifier(s) for a patient's implantable device(s). In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

* * * * *

(iv) *Completeness verification.* Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(ii) of this section without the omission of any of the data classes expressed in the standard in § 170.213.

* * * * *

(8) [Reserved]

(9) * * *

(i) * * *

(A) Respond to requests for patient data (based on an ID or other token) for all of the data classes expressed in the standard in § 170.213 at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard specified in § 170.205(a)(4) and (a)(4)(i) following the CCD document template, including as specified for the following data:

(1) Assessment and plan of treatment. In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in § 170.205(a)(4) and (a)(4)(i); or in accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(2) Goals. In accordance with the ''Goals Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(3) Health concerns. In accordance with the ''Health Concerns Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(4) Unique device identifier(s) for a patient's implantable device(s). In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standard specified in § 170.205(a)(4) and (a)(4)(i).

(10) *Standardized API for patient and population services.* The following technical outcomes and conditions must be met through the demonstration of application programming interface technology.

(i) *Data response.* Respond to requests for data (based on an ID or other token) for each of the resources referenced by the standard adopted in § 170.215(a)(1) and implementation specifications adopted in § 170.215(a)(2) and (3).

(ii) *Search support.* Respond to search requests for data consistent with the search criteria included in the implementation specification adopted in § 170.215(a)(4).

(iii) *App registration.* Enable an application to register with the technology's ''authorization server.''

(iv) *Secure connection.* Establish a secure and trusted connection with an application that requests data in accordance with the standard adopted in § 170.215(a)(5).

(v) *Authentication and app authorization—1st time connection.* The first time an application connects to request data the technology:

(A) *Authentication.* Demonstrates that user authentication occurs during the process of authorizing the application to access FHIR resources in accordance with the standard adopted in § 170.215(b).

(B) *App authorization.* Demonstrates that a user can authorize applications to access a single patient's data as well as multiple patients data in accordance with the implementation specification adopted in § 170.215(a)(5) and issue a refresh token that is valid for a period of at least 3 months.

(vi) *Authentication and app authorization—Subsequent connections.* Demonstrates that an application can access a single patient's data as well as multiple patients data in accordance with the implementation specification adopted in § 170.215(a)(5) without requiring re-authorization and re-authentication when a valid refresh token is supplied and issue a new refresh token for new period no shorter than 3 months.

(vii) *Documentation.* (A) The API(s) must include complete accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) All applicable technical requirements and attributes necessary for an application to be registered with an authorization server.

(B) The documentation used to meet paragraph (g)(10)(vii)(A) of this section must be available via a publicly accessible hyperlink.

(11) *Consent management for APIs.* (i) Respond to requests for data in accordance with:

(A) The standard adopted in § 170.215(c)(1); and

(B) The implementation specification adopted in § 170.215(c)(2).

(ii) *Documentation.* (A) The API(s) must include complete accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) All applicable technical requirements and attributes necessary for an application to be registered with an authorization server.

(B) The documentation used to meet paragraph (g)(11)(ii)(A) of this section must be available via a publicly accessible hyperlink.

* * * * *

■ 17. Add subpart D to part 170 to read as follows:

Subpart D—Conditions and Maintenance of Certification for Health IT Developers

Sec.

170.400 Basis and scope.
170.401 Information blocking.
170.402 Assurances.
170.403 Communications.
170.404 Application programming interfaces.
170.405 Real world testing.
170.406 Attestations.

Subpart D—Conditions and Maintenance of Certification for Health IT Developers

§ 170.400 Basis and scope.

This subpart implements section 3001(c)(5)(D) of the Public Health Service Act by setting forth certain Conditions and Maintenance of Certification requirements for health IT developers participating in the ONC Health IT Certification Program.

§ 170.401 Information blocking.

(a) *Condition of Certification.* A health IT developer must not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj–52 and § 171.103.

(b) *Maintenance of Certification.* [Reserved]

§ 170.402 Assurances.

(a) *Condition of Certification.* (1) A health IT developer must provide assurances satisfactory to the Secretary that the health IT developer will not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj–52 and § 171.103, unless for legitimate purposes specified by the Secretary; or any other action that may inhibit the appropriate exchange, access, and use of electronic health information.

(2) A health IT developer must ensure that its health IT certified under the ONC Health IT Certification Program conforms to the full scope of the certification criteria.

(3) A health IT developer must not take any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the scope of the technology's certification.

(4) A health IT developer that manages electronic health information must certify health IT to the certification criterion in § 170.315(b)(10).

(b) *Maintenance of Certification.* (1) A health IT developer must retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program for:

(i) A period of 10 years beginning from the date each of a developer's health IT is first certified under the Program; or

(ii) If for a shorter period of time, a period of 3 years from the effective date that removes all of the certification criteria to which the developer's health IT is certified from the Code of Federal Regulations.

(2) A health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10) within 24 months of this final rule's effective date or within 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition, whichever is longer.

§ 170.403 Communications.

(a) *Condition of Certification.* (1) A health IT developer may not prohibit or restrict the communication regarding—

(i) The usability of its health IT;

(ii) The interoperability of its health IT;

(iii) The security of its health IT;

(iv) Relevant information regarding users' experiences when using its health IT;

(v) The business practices of developers of health IT related to exchanging electronic health information; and

(vi) The manner in which a user of the health IT has used such technology.

(2) A health IT developer must not engage in any practice that prohibits or restricts a communication regarding the subject matters enumerated in paragraph (a)(1) of this section, unless the practice is specifically permitted by this paragraph and complies with all applicable requirements of this paragraph.

(i) *Unqualified protection for certain communications.* A health IT developer must not prohibit or restrict any person or entity from communicating any information or materials whatsoever (including proprietary information, confidential information, and intellectual property) when the communication is about one or more of the subject matters enumerated in paragraph (a)(1) of this section and is made for any of the following purposes—

(A) Making a disclosure required by law;

(B) Communicating information about adverse events, hazards, and other unsafe conditions to government agencies, health care accreditation organizations, and patient safety organizations;

(C) Communicating information about cybersecurity threats and incidents to government agencies;

(D) Communicating information about information blocking and other unlawful practices to government agencies; or

(E) Communicating information about a health IT developer's failure to comply with a Condition of Certification, or with any other requirement of this part, to ONC or an ONC–ACB.

(ii) *Permitted prohibitions and restrictions.* For communications about one or more of the subject matters enumerated in paragraph (a)(1) of this section that is not entitled to unqualified protection under paragraph (a)(2)(i) of this section, a health IT developer may prohibit or restrict communications only as expressly permitted by paragraphs (a)(2)(ii)(A) through (F) of this section.

(A) *Developer employees and contractors.* A health IT developer may prohibit or restrict the communications of the developer's employees or contractors.

(B) *Non-user-facing aspects of health IT.* A health IT developer may prohibit or restrict communications that disclose information about non-user-facing aspects of the developer's health IT.

(C) *Intellectual property.* A health IT developer may prohibit or restrict communications that would infringe the intellectual property rights existing in the developer's health IT (including third-party rights), provided that—

(1) A health IT developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work; and

(2) A health IT developer does not prohibit the communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section.

(D) *Screenshots.* A health IT developer may require persons who communicate screenshots to—

(1) Not alter screenshots, except to annotate the screenshot, resize it, or to redact the screenshot in accordance with § 170.403(a)(2)(ii)(D)(3) or to conceal protected health information;

(2) Not infringe the intellectual property rights of any third parties, provided that—

(i) The developer has used all reasonable endeavors to secure a license (including the right to sublicense) in respect to the use of the third-party rights by communicators for purposes of the communications protected by this Condition of Certification;

(ii) The developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work;

(iii) The developer has put all potential communicators on sufficient written notice of each aspect of its screen display that contains third-party content that cannot be communicated because the reproduction would infringe the third-party's intellectual property rights; and

(iv) Communicators are permitted to communicate screenshots that have been redacted to not disclose third-party content; and

(3) Redact protected health information, unless the individual has provided all necessary consents or authorizations or the communicator is otherwise authorized, permitted, or required by law to disclose the protected health information.

(E) *Pre-market testing and development.* A health IT developer may prohibit or restrict communications that disclose information or knowledge solely acquired in the course of participating in pre-market product development and testing activities carried out for the benefit of the developer or for the joint benefit of the developer and communicator. A developer must not, once the subject health IT is released or marketed for purposes other than product development and testing, and subject to the permitted prohibitions and restrictions described in paragraph (a)(2)(ii) of this section, prohibit or restrict communications about matters enumerated in paragraph (a)(1) of this section.

(b) *Maintenance of Certification.* (1) *Notice.* Health IT developers must issue a written notice to all customers and those with which it has agreements containing provisions that contravene paragraph (a) of this section:

(i) Within six months of the effective date of the final rule that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer.

(ii) Within one year of the final rule, and annually thereafter until paragraph (b)(2)(ii) of this section is fulfilled, that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer.

(2) *Contracts and agreements.* (i) A health IT developer must not establish or enforce any contract or agreement that contravenes paragraph (a) of this section.

(ii) If a health IT developer has a contract or agreement in existence at the time of the effective date of this final rule that contravenes paragraph (a) of this section, then the developer must in a reasonable period of time, but not later than two years from the effective date of this rule, amend the contract or agreement to remove or void the contractual provision that contravenes paragraph (a) of this section.

§ 170.404 Application programming interfaces.

The following Condition of Certification applies to developers of Health IT Modules certified to any of the certification criteria adopted in § 170.315(g)(7) through (11).

(a) *Condition of Certification.* (1) *General.* An API Technology Supplier must publish APIs and must allow health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws.

(2) *Transparency conditions.* (i) *General.* The business and technical documentation published by an API Technology Supplier must be complete. All documentation published pursuant to paragraph (a)(2)(ii) of this section must be published via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.

(ii) *Terms and conditions.* (A) *Material information.* The API Technology Supplier must publish all terms and conditions for its API technology, including any fees, restrictions, limitations, obligations, registration process requirements, or other similar requirements that would be needed to:

(1) Develop software applications to interact with the API technology;

(2) Distribute, deploy, and enable the use of software applications in production environments that use the API technology;

(3) Use software applications, including to access, exchange, and use electronic health information by means of the API technology;

(4) Use any electronic health information obtained by means of the API technology; and

(5) Register software applications.

(B) *API fees.* Any and all fees charged by an API Technology Supplier for the use of its API technology must be described in detailed, plain language. The description of the fees must include all material information, including but not limited to:

(1) The persons or classes of persons to whom the fee applies;

(2) The circumstances in which the fee applies; and

(3) The amount of the fee, which for variable fees must include the specific variable(s) and methodology(ies) that will be used to calculate the fee.

(C) *Application developer verification.* An API Technology Supplier is permitted to institute a process to verify the authenticity of application developers so long as such process is objective and the same for all application developers and completed within 5 business days of receipt of an application developer's request to register their software application for use with the API Technology Supplier's API technology.

(3) *Permitted fees conditions.* (i) *General conditions.* (A) All fees related to API technology not otherwise permitted by this section are prohibited from being imposed by an API Technology Supplier.

(B) For all permitted fees, an API Technology Supplier must:

(1) Ensure that fees are based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests.

(2) Ensure that fees imposed on API Data Providers are reasonably related to the API Technology Supplier's costs of supplying and, if applicable, supporting API technology to, or at the request of, the API Data Provider to whom the fee is charged.

(3) Ensure that the costs of supplying and, if applicable, supporting the API technology upon which the fee is based are reasonably allocated among all customers to whom the API technology is supplied, or for whom the API technology is supported.

(4) Ensure that fees are not based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the API technology in a way that facilitates competition with the API Technology Supplier.

(ii) *Permitted fee—Development, deployment, and upgrades.* An API Technology Supplier is permitted to charge fees to an API Data Provider to recover the costs reasonably incurred by the API Technology Supplier to develop, deploy, and upgrade API technology for the API Data Provider.

(iii) *Permitted fee—Supporting API uses for purposes other than patient access.* An API Technology Supplier is permitted to charge fees to an API Data Provider to recover the incremental costs reasonably incurred by the API Technology Supplier to support the use of API technology deployed by or on behalf of the API Data Provider. This permitted fee does not include:

(A) Any costs incurred by the API Technology Supplier to support uses of the API technology that facilitate a patient's ability to access, exchange, or use their electronic health information;

(B) Costs associated with intangible assets (including depreciation or loss of value), except the actual development or acquisition costs of such assets; or

(C) Opportunity costs, except for the reasonable forward-looking cost of capital.

(iv) *Permitted fee—Value-added services.* An API Technology Supplier is permitted to charge fees to an API User for value-added services supplied in connection with software that can interact with the API technology, provided that such services are not necessary to efficiently and effectively develop and deploy such software.

(v) *Record-keeping requirements.* An API Technology Supplier must keep for inspection detailed records of any fees charged with respect to the API technology, the methodology(ies) used to calculate such fees, and the specific costs to which such fees are attributed.

(4) *Openness and pro-competitive conditions. General condition.* An API Technology Supplier must grant an API Data Provider the sole authority and autonomy to permit API Users to interact with the API technology deployed by the API Data Provider.

(i) *Non-discrimination.* (A) An API Technology Suppler must provide API technology to API Data Providers on terms that are no less favorable than it provides to itself and its own customers, suppliers, partners, and other persons with whom it has a business relationship.

(B) The terms on which an API Technology Supplier provides API technology must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests.

(C) An API Technology Supplier must not offer different terms or service on the basis of:

(1) Whether the API User with whom an API Data Provider has a relationship is a competitor, potential competitor, or will be using electronic health information obtained via the API technology in a way that facilitates competition with the API Technology Supplier.

(2) The revenue or other value the API User with whom an API Data Provider has a relationship may derive from access, exchange, or use of electronic health information obtained by means of API technology.

(ii) *Rights to access and use API technology.* (A) An API Technology Supplier must have and, upon request, must grant to API Data Providers and their API Users all rights that may be reasonably necessary to access and use API technology in a production environment, including:

(1) For the purposes of developing products or services that are designed to be interoperable with the API Technology Supplier's health information technology or with health information technology under the API Technology Supplier's control;

(2) Any marketing, offering, and distribution of interoperable products and services to potential customers and users that would be needed for the API technology to be used in a production environment; and

(3) Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.

(B) An API Technology Supplier must not condition any of the rights described in paragraph (a)(4)(ii)(A) of this section on the requirement that the recipient of the rights do, or agree to do, any of the following:

(1) Pay a fee to license such rights, including but not limited to a license fee, royalty, or revenue-sharing arrangement.

(2) Not compete with the API Technology Supplier in any product, service, or market.

(3) Deal exclusively with the API Technology Supplier in any product, service, or market.

(4) Obtain additional licenses, products, or services that are not related to or can be unbundled from the API technology.

(5) License, grant, assign, or transfer any intellectual property to the API Technology Supplier.

(6) Meet additional developer or product certification requirements.

(7) Provide the API Technology Supplier or its technology with reciprocal access to application data.

(iii) *Service and support obligations.* An API Technology Supplier must provide all support and other services reasonably necessary to enable the effective development, deployment, and use of API technology by API Data Providers and their API Users in production environments.

(A) *Changes and updates to API technology.* An API Technology Supplier must make reasonable efforts to maintain the compatibility of its API technology and to otherwise avoid disrupting the use of API technology in production environments.

(B) *Changes to terms and conditions.* Except as exigent circumstances require, prior to making changes or updates to its API technology or to the terms and conditions thereof, an API Technology Supplier must provide notice and a reasonable opportunity for its API Data Provider customers and registered application developers to update their applications to preserve compatibility with API technology and to comply with applicable terms and conditions.

(b) *Maintenance of Certification.* (1) *Registration for production use.* An API Technology Supplier with health IT certified to the certification criterion adopted in § 170.315(g)(10) must register and enable all applications for production use within 1 business day of completing its verification of an application developer's authenticity, pursuant to paragraph (a)(2)(ii)(C) of this section.

(2) *Service Base URL publication.* API Technology Supplier must support the publication of Service Base URLs for all of its customers, regardless of those that are centrally managed by the API Technology Supplier or locally deployed by an API Data Provider, and make such information publicly available (in a computable format) at no charge.

(3) *Rollout of (g)(10)-Certified APIs.* An API Technology Supplier with API technology previously certified to the certification criterion in § 170.315(g)(8) must provide all API Data Providers with such API technology deployed with API technology certified to the certification criterion in § 170.315(g)(10) within 24 months of this final rule's effective date.

§ 170.405 Real world testing.

(a) *Condition of Certification.* A health IT developer with Health IT Modules to be certified to any one or more 2015 Edition certification criteria in § 170.315(b), (c)(1) through (3), (e)(1), (f), (g)(7) through (11), and (h) must successfully test the real world use of those Health IT Module(s) for interoperability (as defined in 42 U.S.C. 300jj(9) and § 170.102) in the type of setting in which such Health IT Module(s) would be/is marketed.

(b) *Maintenance of Certification.* (1) *Real world testing plan submission.* A health IT developer must submit an annual real world testing plan to its ONC–ACB via a publicly accessible hyperlink no later than December 15 of each calendar year for each of its certified 2015 Edition Health IT Modules that include certification criteria referenced in paragraph (a) of this section.

(i) The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.

(ii) The plan must include all health IT certified to the 2015 Edition through August 31st of the preceding year.

(iii) The plan must address the following for each of the certification criteria identified in paragraph (a) of this section that are included in the Health IT Module's scope of certification:

(A) The testing method(s)/methodology(ies) that will be used to demonstrate real world interoperability and conformance to the certification criteria's requirements, including scenario- and use case-focused testing;

(B) The care setting(s) that will be tested for real world interoperability and an explanation for the health IT developer's choice of care setting(s) to test;

(C) The timeline and plans for any voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process.

(D) A schedule of key real world testing milestones;

(E) A description of the expected outcomes of real world testing;

(F) At least one measurement/metric associated with the real world testing; and

(G) A justification for the health IT developer's real world testing approach.

(2) *Real world testing results reporting.* A health IT developer must submit real world testing results to its ONC–ACB via a publicly accessible hyperlink no later than January 31 each calendar year for each of its certified 2015 Edition Health IT Modules that include certification criteria referenced in paragraph (a) of this section. The real world testing results must report the following for each of the certification criteria identified in paragraph (a) of this section that are included in the Health IT Module's scope of certification:

(i) The method(s) that was used to demonstrate real world interoperability;

(ii) The care setting(s) that was tested for real world interoperability;

(iii) The voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process.

(iv) A list of the key milestones met during real world testing;

(v) The outcomes of real world testing including a description of any challenges encountered during real world testing; and

(vi) At least one measurement/metric associated with the real world testing.

(3) *USCDI Updates for C–CDA.* A health IT developer with health IT certified to § 170.315(b)(1), (e)(1), (g)(6), (f)(5), and/or (g)(9) prior to the effective date of this final rule must:

(i) Update their certified health IT to be compliant with the revised versions of these criteria adopted in this final rule; and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(3)(i) of this section within 24 months of the effective date of this final rule.

(4) *C–CDA Companion Guide Updates.* A health IT developer with health IT certified to § 170.315(b)(1), (b)(2), (b)(9), (e)(1), (g)(6), and/or (g)(9) prior to the effective date of this final rule must:

(i) Update their certified health IT to be compliant with the revised versions of these criteria adopted in this final rule; and

(ii) Provide its customers of the previously certified health IT with certified health IT that meets paragraph (b)(4)(i) of this section within 24 months of the effective date of this final rule.

(5) *Voluntary standards and implementation specifications updates.* A health IT developer subject to paragraph (a) of this section that voluntary updates its certified health IT to a new version of an adopted standard that is approved by the National Coordinator through the Standards Version Advancement Process must:

(i) Provide advance notice to all affected customers and its ONC–ACB—

(A) Expressing its intent to update the software to the more advanced version of the standard approved by the National Coordinator;

(B) The developer's expectations for how the update will affect interoperability of the affected Health IT Module as it is used in the real world;

(C) Whether the developer intends to continue to support the certificate for the existing certified Health IT Module version for some period of time and how long or if the existing certified Health IT Module version will be deprecated; and

(ii) Successfully demonstrate conformance with approved more recent versions of the standard(s) or implementation specification(s) included in applicable 2015 Edition certification criterion specified in paragraph (a) of this section.

§ 170.406 Attestations.

(a) *Condition of Certification.* A health IT developer must provide the Secretary with an attestation of compliance with the Conditions and Maintenance of Certification requirements specified in §§ 170.401 through 170.405 at the time of certification. Specifically, a health IT developer must attest to:

(1) Having not taken any action that constitutes information blocking as defined in 42 U.S.C. 300jj–52 and § 171.103;

(2) Having provided assurances satisfactory to the Secretary that they will not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj–52 and § 171.103, unless for legitimate purposes specified by the Secretary; or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

(3) Not prohibiting or restricting the communications regarding—

(i) The usability of its health IT;

(ii) The interoperability of its health IT;

(iii) The security of its health IT;

(iv) Relevant information regarding users' experiences when using its health IT;

(v) The business practices of developers of health IT related to exchanging electronic health information; and

(vi) The manner in which a user of the health IT has used such technology; and

(4) Having published application programming interfaces (APIs) and allowing health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws;

(5) Ensuring that its health IT allows for health information to be exchanged, accessed, and used, in the manner described in paragraph (a)(4) of this section; and

(6) Having undertaken real world testing of its Health IT Module(s) for interoperability (as defined in 42 U.S.C. 300jj(9)) in the type of setting in which such Health IT Module(s) will be/is marketed.

(b) *Maintenance of Certification.* (1) A health IT developer must attest to compliance with §§ 170.401 through 170.405 at the time of certification.

(2) A health IT developer must attest semiannually to compliance with §§ 170.401 through 170.405 for all its health IT that had an active certification at any time under the ONC Health IT Certification Program during the prior six months.

§ 170.501 [Amended]

■ 18. Amend § 170.501 as follows:

■ a. In paragraph (a) remove the phrase ''Complete EHRs'';

■ b. In paragraph (b) remove the phrase ''Complete EHRs and''; and
■ c. Remove and reserve paragraph (c).

§ 170.502 [Amended]

■ 19. Amend § 170.502 as follows:
■ a. In the definition of ''Deployment site'', remove the phrase ''Complete EHR,'';
■ b. In the definition of ''Development site'', remove the phrase ''Complete EHR,'';
■ c. In the definition of ''Gap certification'', remove the phrase ''Complete EHR or'';
■ d. Remove the definition of ''ONC-Approved Accreditor or ONC–AA'';
■ e. In the definition of ''ONC-Authorized Certification Body or ONC–ACB'', remove the phrase ''Complete EHRs,''; and
■ f. In the definition of ''ONC-Authorized Testing Lab or ONC–ATL'', remove the phrase ''Complete EHRs and''.

§ 170.503 [Removed and Reserved]

■ 20. Remove and reserve § 170.503.

§ 170.504 [Removed and Reserved]

■ 21. Remove and reserve § 170.504.
■ 22. Revise § 170.505 to read as follows:

§ 170.505 Correspondence.

(a) Correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified. The official date of receipt of any email between ONC or the National Coordinator and an applicant for ONC–ACB status, an applicant for ONC–ATL status, an ONC–ACB, an ONC–ATL, health IT developer, or a party to any proceeding under this subpart is the date on which the email was sent.

(b) In circumstances where it is necessary for an applicant for ONC–ACB status, an applicant for ONC–ATL status, an ONC–ACB, an ONC–ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or the National Coordinator by regular, express, or certified mail, the official date of receipt for all parties will be the date of the delivery confirmation to the address on record.

§ 170.510 [Amended]

■ 23. Amend § 170.510 by removing paragraph (a) and redesignating paragraphs (b) and (c) as paragraphs (a) and (b).
■ 24. Amend § 170.520 by revising paragraph (a)(3) to read as follows:

§ 170.520 Application.

(a) * * *

(3) Documentation that confirms that the applicant has been accredited to ISO/IEC 17065, with an appropriate scope, by any accreditation body that is a signatory to the Multilateral Recognition Arrangement (MLA) with the International Accreditation Forum (IAF) (incorporated by reference in § 170.599).

* * * * *

■ 25. Amend § 170.523 as follows:
■ a. Revise paragraph (a);
■ b. In paragraph (f) introductory text, add a header and remove the phrase, ''Complete EHRs,'';
■ c. Removing and reserve paragraph (f)(2);
■ d. Revise paragraphs (g) and (h);
■ e. In paragraph (k) introductory text, remove the phrase ''Complete EHRs and'';
■ f. In paragraph (k)(1) introductory text, add a header and remove the phrase ''Complete EHR or'';
■ g. Remove paragraphs (k)(1)(ii)(B), and (k)(1)(iii)(B);
■ h. Revise paragraph (k)(1)(iii)(A);
■ i. Remove paragraphs (k)(1)(iv)(B) and (C);
■ j. Remove and reserve paragraphs (k)(2) and (3);
■ k. Revise paragraph (k)(4);
■ l. Revise paragraphs (m)(1) and (2);
■ m. Add paragraphs (m)(3) and (4));
■ n. In paragraph (o), remove the phrase ''Complete EHR or''; and
■ o. Add paragraphs (p) through (t).

The revisions and additions read as follows:

§ 170.523 Principles of proper conduct for ONC–ACBs.

* * * * *

(a) *Accreditation.* Maintain its accreditation in good standing to ISO/IEC 17065 (incorporated by reference in § 170.599).

* * * * *

(f) *Reporting.* * * *

(2) [Reserved]

(g) *Records retention.* (1) Retain all records related to the certification of Complete EHRs and Health IT Modules to an edition of certification criteria beginning with the codification of an edition of certification criteria in the Code of Federal Regulations through a minimum of 3 years from the effective date that removes the applicable edition from the Code of Federal Regulations; and

(2) Make the records available to HHS upon request during the retention period described in paragraph (g)(1) of this section;

(h) *Testing.* Only certify Health IT Modules that have been:

(1) Tested, using test tools and test procedures approved by the National Coordinator, by an:

(i) ONC–ATL;

(ii) ONC–ATL, NVLAP-accredited testing laboratory under the ONC Health IT Certification Program, and/or an ONC–ATCB for the purposes of performing gap certification; or

(2) Evaluated by it for compliance with a conformance method approved by the National Coordinator.

* * * * *

(k) *Disclosures.* * * *

(1) * * *

(ii) For a Health IT Module certified to 2015 Edition health IT certification criteria, the information specified by paragraphs (f)(1)(i), (vi) through (viii), (xv), and (xvi) of this section as applicable for the specific Health IT Module.

(iii) In plain language, a detailed description of all known material information concerning additional types of costs or fees that a user may be required to pay to implement or use the Health IT Module's capabilities, whether to meet provisions of HHS programs requiring the use of certified health IT or to achieve any other use within the scope of the health IT's certification. The additional types of costs or fees required to be disclosed include but are not limited to costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a health IT developer (or any third party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.

* * * * *

(2) [Reserved]

(3) [Reserved]

(4) A certification issued to a Health IT Module based solely on the applicable certification criteria adopted by the ONC Health IT Certification Program must be separate and distinct from any other certification(s) based on other criteria or requirements.

* * * * *

(m) * * *

(1) All adaptations of certified Health IT Modules;

(2) All updates made to certified Health IT Modules affecting the capabilities in certification criteria to which the ''safety-enhanced design'' criteria apply;

(3) All updates made to certified Health IT Modules in compliance with § 170.405(b)(3) and (4); and;

(4) All voluntary standards updates successfully made to certified Health IT Modules per § 170.405(b)(5).

* * * * *

(p) *Real world testing.* (1) Review and confirm that applicable health IT developers submit real world testing plans in accordance with § 170.405(b)(1).

(2) Review and confirm that applicable health IT developers submit real world testing results in accordance with § 170.405(b)(2).

(3) Submit real world testing plans by December 15 of each calendar year and results by April 1 of each calendar year to ONC for public availability.

(q) *Attestations.* Review and submit health IT developer Conditions and Maintenance of Certification attestations made in accordance with § 170.406 to ONC for public availability.

(r) *Test results from ONC–ATLs.* Accept test results from any ONC–ATL that is:

(1) In good standing under the ONC Health IT Certification Program, and

(2) Compliant with its ISO 17025 accreditation requirements.

(s) *Information for direct review.* Report to ONC, no later than a week after becoming aware of, any information that could inform whether ONC should exercise direct review under § 170.580(a).

(t) *Standards Voluntary Advancement Process Module Updates Notices.* Ensure health IT developers opting to take advantage of the Standards Version Advancement Process flexibility per § 170.405(b)(5) provide timely advance written notice to the ONC–ACB and all affected customers.

(1) Maintain a record of the date of issuance and the content of developers' § 170.405(b)(5) notices; and

(2) Timely post content of each § 170.405(b)(5) notice received publicly on the CHPL attributed to the certified Health IT Module(s) to which it applies.

■ 26. Amend § 170.524 as follows:

■ a. Revise paragraph (f); and

■ b. In paragraph (h)(3), remove the phrase ''Complete EHRs and/or''. The revisions and additions read as follows:

§ 170.524 Principles of proper conduct for ONC–ATLs.

* * * * *

(f) *Records retention.* (1) Retain all records related to the testing of Complete EHRs and/or Health IT Modules to an edition of certification criteria beginning with the codification of an edition of certification criteria in the Code of Federal Regulations through a minimum of 3 years from the effective date that removes the applicable edition from the Code of Federal Regulations; and

(2) Make the records available to HHS upon request during the retention period described in paragraph (f)(1) of this section;

* * * * *

§ 170.545 [Removed and Reserved]

■ 27. Remove and reserve § 170.545.

■ 28. Amend § 170.550 as follows:

■ a. Add paragraph (e);

■ b. Remove and reserve paragraph (f);

■ c. Add paragraph (g)(5);

■ d. Revise paragraphs (h)(3)(i), (iii), (v), (vii); and

■ e. Add paragraphs (h)(3)(ix) and (l).

The additions and revisions read as follows:

§ 170.550 Health IT Module certification.

* * * * *

(e) ONC–ACBs must provide an option for certification of Health IT Modules to any one or more of the criteria referenced in § 170.405(a) based on newer versions of standards included in the criteria which have been approved by the National Coordinator for use in certification through the Standards Version Advancement Process.

(f) [Reserved]

(g) * * *

(5) Section 170.315(b)(10) when the health IT developer of the health IT presented for certification produces and electronically manages electronic health information.

(h) * * *

(3) * * *

(i) Section 170.315(a)(1) through (3), (5) through (8), (11), and (12) are also certified to the certification criteria specified in § 170.315(d)(1) through (7). Section 170.315(a)(4), (9), (10), and (13) are also certified to the certification criteria specified in § 170.315(d)(1) through (3), and (5) through (7).

* * * * *

(iii) Section 170.315(c) is also certified to the certification criteria specified in § 170.315(d)(1), (2)(i)(A), (B), (ii) through (v), (3), and (5);

* * * * *

(v) Section 170.315(e)(2) and (3) is also certified to the certification criteria specified in § 170.315(d)(1), (d)(2)(i)(A), (B), (ii) through (v), (3), (5), and (9);

* * * * *

(vii) Section 170.315(g)(7) through (11) is also certified to the certification criteria specified in § 170.315(d)(1) and (9); and (d)(2)(i)(A), (2)(i)(B), 2(ii) through (v), or (10);

(viii) Section 170.315(h) is also certified to the certification criteria specified in § 170.315(d)(1), (2)(i)(A), (2)(i)(B), (2)(ii) through (v), and (3); and

* * * * *

(ix) If applicable, any criterion adopted in § 170.315 is also certified to the certification criteria specified in § 170.315(d)(12) and/or (13).

* * * * *

(l) *Conditions of Certification Attestations.* Before issuing a certification, ensure that the health IT developer of the Health IT Module has met its responsibilities under subpart D of this part.

§ 170.555 [Amended]

■ 29. Amend § 170.555 as follows:

■ a. In paragraph (a), remove the reference ''Complete EHRs and/or'';

■ b. Revise paragraph (b)(1); and

■ c. In paragraph (b)(2), remove the reference ''certified Complete EHR or''. The revisions read as follows:

§ 170.555 Certification to newer versions of certain standards.

* * * * *

(b) * * *

(1) ONC–ACBs are not required to certify Complete EHRs and/or Health IT Module(s) according to newer versions of standards adopted and named in subpart B of this part, unless:

(i) The National Coordinator identifies a new version through the Standards Version Advancement Process and a health IT developer voluntarily elects to update its certified health IT to the new version in accordance with § 170.405(b)(5); or

(ii) The new version is incorporated by reference in § 170.299.

* * * * *

■ 30. Amend § 170.556 as follows:

■ a. Revise paragraph (a) introductory text;

■ b. In paragraph (b) introductory text, remove the phrase ''certified Complete EHR or'';

■ c. Revise paragraph (c) introductory text;

■ d. In paragraph (c)(1), remove the phrases ''certified Complete EHR or'' and ''Complete EHR or'';

■ e. Remove and reserve paragraph (c)(2);

■ f. In paragraph (c)(3), remove the phrase ''certified Complete EHRs and'';

■ g. In paragraphs (c)(4)(i) and (ii), remove the phrase ''certified Complete EHR or'';

■ h. Remove paragraphs (c)(5) and (6);

■ i. In paragraph (d)(1), remove the phrase ''Complete EHR or'';

■ j. In paragraph (d)(3)(ii), remove the phrase ''certified Complete EHR or'';

■ k. In paragraph (d)(5) introductory text, remove the phrase ''Complete EHR or'';

■ l. In paragraph (d)(6), remove the phrases ''certified Complete EHR or'' and ''Complete EHR or'';

■ m. In paragraph (e)(3), remove the phrase ''Complete EHR or''; and

■ n. In paragraph (f), remove the phrase ''certified Complete EHR or''. The revisions and additions read as follows:

§ 170.556 In-the-field surveillance and maintenance of certification for Health IT.

(a) *In-the-field surveillance.* Consistent with its accreditation to ISO/IEC 17065 and the requirements of this subpart, an ONC–ACB must initiate surveillance ''in the field'' as necessary to assess whether a certified Health IT Module continues to conform to the requirements in subparts A, B, C and E of this part once the certified Health IT Module has been implemented and is in use in a production environment.

* * * * *

(c) *Randomized surveillance.* During each calendar year surveillance period, an ONC–ACB may conduct in-the-field surveillance for certain randomly selected Health IT Modules to which it has issued a certification.

* * * * *

(2) [Reserved]

* * * * *

§§ 170.560, 170.565, and 170.570 [Amended]

■ 31. In the table below, for each section and paragraph indicated in the first two columns, remove the phrase indicated in the third column:

Section	Paragraphs	Remove
§ 170.560	(a)(2)	''Complete EHRs and/or''.
§ 170.565	(d)(ii) and (d)(iii)	''Complete EHRs or''.
§ 170.565	(h)(2)(iii)	''Complete EHRs and''.
§ 170.570	(a), (b)(2), (c) introductory text, (c)(1), and (c)(2)	''Complete EHRs and/or''.

§ 170.575 [Removed and Reserved]

■ 32. Remove and reserve § 170.575.

■ 33. Amend § 170.580 as follows:

■ a. Revise paragraph (a)(1) and the headings of paragraphs (a)(2)(i) and (ii);

■ b. Add paragraph (a)(2)(iii);

■ c. Revise paragraphs (a)(3)(i), (iv), and (v);

■ d. Add paragraph (a)(4);

■ e. Revise paragraphs (b)(1)(i) and (iii)(D);

■ f. Revise paragraphs (b)(2)(i);

■ g. Revise paragraphs (b)(3)(i) and (ii);

■ h. Add paragraphs (b)(3)(iii) and (iv);

■ i. Revise paragraph (c)(1);

■ j. In paragraphs (d)(1), (d)(2)(i)(C), and (d)(4), remove the phrase ''Complete EHR or'';

■ k. In paragraph (d)(5), remove the phrase ''Complete EHRs or'';

■ l. Revise paragraph (e)(1) introductory text;

■ m. Revise paragraph (f)(1);

■ n. In paragraph (f)(2)(i)(C) by removing the reference ''Complete EHR or'';

■ o. Revise paragraphs (g)(1) introductory text, (g)(1)(i), (g)(2), (g)(3)(i), (g)(4), (g)(5)(i), and (g)(6)(v).

The additions and revisions read as follows:

§ 170.580 ONC review of certified health IT or a health IT developer's actions.

(a) * * *

(1) *Purpose.* ONC may directly review certified health IT or a health IT developer's actions or practices to determine whether either conform to the requirements of the ONC Health IT Certification Program.

(2) * * *

(i) *Certified health IT causing or contributing to unsafe conditions.* * * *

* * * * *

(ii) *Impediments to ONC–ACB oversight of certified health IT.* * * *

* * * * *

(iii) *Noncompliance with Conditions and Maintenance of Certification.* ONC may initiate direct review under this section if it has a reasonable belief that a health IT developer has not complied with a Condition or Maintenance of Certification requirement under subpart D of this part.

(3) * * *

(i) ONC's review of certified health IT or a health IT developer's actions or practices is independent of, and may be in addition to, any surveillance of certified health IT conducted by an ONC–ACB.

(4) *Coordination with the Office of Inspector General.* (i) ONC may coordinate its review of a claim of information blocking with the Office of Inspector General or defer to the Office of Inspector General to lead a review of a claim of information blocking.

(ii) ONC may rely on Office of Inspector General findings to form the basis of a direct review action.

* * * * *

(iv) An ONC–ACB and ONC–ATL shall provide ONC with any available information that ONC deems relevant to its review of certified health IT or a health IT developer's actions or practices.

(v) ONC may end all or any part of its review of certified health IT or a health IT developer's actions or practices under this section at any time and refer the applicable part of the review to the relevant ONC–ACB(s) if ONC determines that doing so would serve the effective administration or oversight of the ONC Health IT Certification Program.

(b) * * *

(1) * * *

(i) *Circumstances that may trigger notice of potential non-conformity.* At any time during its review of certified health IT or a health IT developer's actions or practices under paragraph (a) of this section, ONC may send a notice of potential non-conformity if it has a reasonable belief that certified health IT or a health IT developer may not conform to the requirements of the ONC Health IT Certification Program.

* * * * *

(iii) * * *

(D) Issue a notice of proposed termination if the health IT is under review in accordance with paragraphs (a)(2)(i) or (ii) of this section.

(2) * * *

(i) *Circumstances that may trigger notice non-conformity.* At any time during its review of certified health IT or a health IT developer's actions or practices under paragraph (a) of this section, ONC may send a notice of non-conformity to the health IT developer if it determines that certified health IT or a health IT developer's actions or practices does not conform to the requirements of the ONC Health IT Certification Program.

* * * * *

(*3*) * * *

(i) All records related to the development, testing, certification, implementation, maintenance and use of its certified health IT;

(ii) Any complaint records related to the certified health IT;

(iii) All records related to the Condition(s) and Maintenance of Certification requirements, including marketing and distribution records, communications, and contracts; and

(iv) Any other relevant information.

(c) * * *

(1) *Applicability.* If ONC determines that certified health IT or a health IT developer's action or practice does not conform to requirements of the ONC Health IT Certification Program, ONC shall notify the health IT developer of its determination and require the health

IT developer to submit a proposed corrective action plan.

* * * * *

(e) * * *

(1) *Applicability.* Excluding situations of noncompliance with a Condition or Maintenance of Certification requirement under subpart D of this part, ONC may propose to terminate a certification issued to a Health IT Module if:

* * * * *

(f) * * *

(1) *Applicability.* The National Coordinator may terminate a certification if:

(i) A determination is made that termination is appropriate after considering the information provided by the health IT developer in response to the proposed termination notice;

(ii) The health IT developer does not respond in writing to a proposed termination notice within the timeframe specified in paragraph (e)(3) of this section; or

(iii) A determination is made that the health IT developer is noncompliant with a Condition or Maintenance of Certification requirement under subpart D of this part or for the following circumstances when ONC exercises direct review under paragraph (a)(2)(iii) of this section:

(A) The health IT developer fails to timely respond to any communication from ONC, including, but not limited to:

(1) Fact-finding;

(2) A notice of potential non-conformity within the timeframe established in accordance with paragraph (b)(1)(ii)(A)(*3*) of this section; or

(3) A notice of non-conformity within the timeframe established in accordance with paragraph (b)(2)(ii)(A)(*3*) of this section.

(B) The information or access provided by the health IT developer in response to any ONC communication, including, but not limited to: Fact-finding, a notice of potential non-conformity, or a notice of non-conformity is insufficient or incomplete;

(C) The health IT developer fails to cooperate with ONC and/or a third party acting on behalf of ONC;

(D) The health IT developer fails to timely submit in writing a proposed corrective action plan;

(E) The health IT developer fails to timely submit a corrective action plan that adequately addresses the elements required by ONC as described in paragraph (c) of this section;

(F) The health IT developer does not fulfill its obligations under the corrective action plan developed in accordance with paragraph (c) of this section; or

(G) ONC concludes that the non-conformity(ies) cannot be cured.

* * * * *

(g) * * *

(1) *Basis for appeal.* A health IT developer may appeal an ONC determination to suspend or terminate a certification issued to a Health IT Module and/or an ONC determination to issue a certification ban under § 170.581(a)(2) if the health IT developer asserts:

(i) ONC incorrectly applied ONC Health IT Certification Program requirements for a

(A) Suspension;

(B) Termination; or

(C) Certification ban under § 170.581(a)(2); or

* * * * *

(2) *Method and place for filing an appeal.* A statement of intent to appeal followed by a request for appeal must be submitted to ONC in writing by an authorized representative of the health IT developer subject to the determination being appealed. The statement of intent to appeal and request for appeal must be filed in accordance with the requirements specified in the notice of:

(i) Termination;

(ii) Suspension; or

(iii) Certification ban under § 170.581(a)(2).

(3) * * *

(i) A statement of intent to appeal must be filed within 10 days of a health IT developer's receipt of the notice of:

(A) Suspension;

(B) Termination; or

(C) Certification ban under § 170.581(a)(2).

* * * * *

(4) *Effect of appeal.* (i) A request for appeal stays the termination of a certification issued to a Health IT Module, but the Health IT Module is prohibited from being marketed, licensed, or sold as ''certified'' during the stay.

(ii) A request for appeal does not stay the suspension of a Health IT Module.

(iii) A request for appeal stays a certification ban issued under § 170.581(a)(2).

(5) * * *

(i) The hearing officer may not review an appeal in which he or she participated in the initial suspension, termination, or certification ban determination or has a conflict of interest in the pending matter.

* * * * *

(6) * * *

(v) ONC will have an opportunity to provide the hearing officer with a written statement and supporting documentation on its behalf that clarifies, as necessary, its determination to suspend or terminate the certification or issue a certification ban.

* * * * *

■ 34. Revise § 170.581 to read as follows:

§ 170.581 Certification ban.

(a) *Circumstances trigger a certification ban.* The certification of any of a health IT developer's health IT is prohibited when:

(1) The certification of one or more of the health IT developer's Complete EHRs or Health IT Modules is:

(i) Terminated by ONC under the ONC Health IT Certification Program;

(ii) Withdrawn from the ONC Health IT Certification Program by an ONC–ACB because the health IT developer requested it to be withdrawn when the health IT developer's health IT was the subject of a potential non-conformity or non-conformity as determined by ONC;

(iii) Withdrawn by an ONC–ACB because of a non-conformity with any of the certification criteria adopted by the Secretary under subpart C of this part;

(iv) Withdrawn by an ONC–ACB because the health IT developer requested it to be withdrawn when the health IT developer's health IT was the subject of surveillance for a certification criterion or criteria adopted by the Secretary under subpart C of this part, including notice of pending surveillance; or

(2) ONC determines a certification ban is appropriate per its review under § 170.580(a)(2)(iii).

(b) *Notice of certification ban.* When ONC decides to issue a certification ban to a health IT developer, ONC will notify the health IT developer of the certification ban through a notice of certification ban. The notice of certification ban will include, but may not be limited to:

(1) An explanation of the certification ban;

(2) Information supporting the certification ban;

(3) Instructions for appealing the certification ban if banned in accordance with paragraph (a)(2) of this section; and

(4) Instructions for requesting reinstatement into the ONC Health IT Certification Program, which would lift the certification ban.

(c) *Effective date of certification ban.* (1) A certification ban will be effective immediately if banned under paragraphs (a)(1) of this section.

(2) For certification bans issued under paragraph (a)(2) of this section, the ban

will be effective immediately after the following applicable occurrence:

(i) The expiration of the 10-day period for filing a statement of intent to appeal in § 170.580(g)(3)(i) if the health IT developer does not file a statement of intent to appeal.

(ii) The expiration of the 30-day period for filing an appeal in § 170.580(g)(3)(ii) if the health IT developer files a statement of intent to appeal, but does not file a timely appeal.

(iii) A final determination to issue a certification ban per § 170.580(g)(7) if a health IT developer files an appeal timely.

(d) *Reinstatement.* The certification of a health IT developer's health IT subject to the prohibition in paragraph (a) of this section may commence once the following conditions are met.

(1) A health IT developer must request ONC's permission in writing to participate in the ONC Health IT Certification Program.

(2) The request must demonstrate that the customers affected by the certificate termination, certificate withdrawal, or non-compliance with a Condition or Maintenance of Certification have been provided appropriate remediation.

(3) For non-compliance with a Condition or Maintenance of Certification requirement, the non-compliance must be resolved.

(4) ONC is satisfied with the health IT developer's demonstration under paragraph (d)(2) of this section that all affected customers have been provided with appropriate remediation and grants reinstatement into the ONC Health IT Certification Program.

■ 35. Add part 171 to read as follows:

PART 171—INFORMATION BLOCKING

Subpart A—General Provisions

Sec.

171.100 Basis and purpose.
171.101 Applicability.
171.102 Definitions.
171.103 Information blocking.

Subpart B—Exceptions for Reasonable and Necessary Activities That Do Not Constitute Information Blocking

171.200 Availability and effect of exceptions.
171.201 Exception—Preventing harm.
171.202 Exception—Promoting the privacy of electronic health information.
171.203 Exception—Promoting the security of electronic health information.
171.204 Exception—Recovering costs reasonably incurred.
171.205 Exception—Responding to requests that are infeasible.
171.206 Exception—Licensing of interoperability elements on reasonable and non-discriminatory terms.
§ 171.207 Exception—Maintaining and improving health IT performance.

Authority: 42 U.S.C. 300jj–52; 5 U.S.C. 552.

Subpart A—General Provisions

§ 171.100 Statutory basis and purpose.

(a) *Basis.* This part implements section 3022 of the Public Health Service Act, 42 U.S.C. 300jj–52.

(b) *Purpose.* The purpose of this part is to establish exceptions for reasonable and necessary activities that do not constitute ''information blocking,'' as defined by section 3022(a)(1) of the Public Health Service Act, 42 U.S.C. 300jj–52.

§ 171.101 Applicability.

This part applies to health care providers, health IT developers of certified health IT, health information exchanges, and health information networks, as those terms are defined in § 171.102.

§ 171.102 Definitions.

For purposes of this part:

Access means the ability or means necessary to make electronic health information available for use, including the ability to securely and efficiently locate and retrieve information from any and all source systems in which the information may be recorded or maintained.

Actor means a health care provider, health IT developer of certified health IT, health information exchange, or health information network.

API Data Provider is defined as it is in § 170.102.

API Technology Supplier is defined as it is in § 170.102.

Electronic Health Information (EHI) means—

(1) Electronic protected health information; and

(2) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Electronic media is defined as it is in 45 CFR 160.103.

Electronic protected health information (ePHI) is defined as it is in 45 CFR 160.103.

Exchange means the ability for electronic health information to be transmitted securely and efficiently between and among different technologies, systems, platforms, or networks in a manner that allows the information to be accessed and used.

Fee means any present or future obligation to pay money or provide any other thing of value.

Health care provider has the same meaning as ''health care provider'' at 42 U.S.C. 300jj.

Health Information Exchange or *HIE* means an individual or entity that enables access, exchange, or use of electronic health information primarily between or among a particular class of individuals or entities or for a limited set of purposes.

Health Information Network or *HIN* means an individual or entity that satisfies one or both of the following—

(1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

(2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

Health IT developer of certified health IT means an individual or entity that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which had, at the time it engaged in a practice that is the subject of an information blocking claim, health information technology (one or more) certified under the ONC Health IT Certification Program.

Information blocking is defined as it is in § 171.103 and 42 U.S.C. 300jj–52(a).

Interfere with means to prevent, materially discourage, or otherwise inhibit access, exchange, or use of electronic health information.

Interoperability element means—

(1) Any functional element of a health information technology, whether hardware or software, that could be used to access, exchange, or use electronic health information for any purpose, including information transmitted by or maintained in disparate media, information systems, health information exchanges, or health information networks.

(2) Any technical information that describes the functional elements of technology (such as a standard, specification, protocol, data model, or schema) and that a person of ordinary skill in the art may require to use the functional elements of the technology,

including for the purpose of developing compatible technologies that incorporate or use the functional elements.

(3) Any technology or service that may be required to enable the use of a compatible technology in production environments, including but not limited to any system resource, technical infrastructure, or health information exchange or health information network element.

(4) Any license, right, or privilege that may be required to commercially offer and distribute compatible technologies and make them available for use in production environments.

(5) Any other means by which electronic health information may be accessed, exchanged, or used.

Permissible purpose means a purpose for which a person is authorized, permitted, or required to access, exchange, or use electronic health information under applicable law.

Person is defined as it is in 45 CFR 160.103.

Protected health information is defined as it is in 45 CFR 160.103.

Practice means one or more related acts or omissions by an actor.

Use means the ability of health IT or a user of health IT to access relevant electronic health information; to comprehend the structure, content, and meaning of the information; and to read, write, modify, manipulate, or apply the information to accomplish a desired outcome or to achieve a desired purpose.

§ 171.103 Information blocking.

Information blocking means a practice that—

(a) Except as required by law or covered by an exception set forth in subpart B of this part, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(b) If conducted by a health information technology developer, health information exchange, or health information network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

(c) If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

Subpart B—Exceptions for Reasonable and Necessary Activities That Do Not Constitute Information Blocking

§ 171.200 Availability and effect of exceptions.

A practice shall not be treated as information blocking if the actor satisfies an exception to the information blocking provision by meeting all applicable requirements and conditions of the exception at all relevant times.

§ 171.201 Exception—Preventing harm.

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) The actor must have a reasonable belief that the practice will directly and substantially reduce the likelihood of harm to a patient or another person arising from—

(1) Corrupt or inaccurate data being recorded or incorporated in a patient's electronic health record;

(2) Misidentification of a patient or patient's electronic health information; or

(3) Disclosure of a patient's electronic health information in circumstances where a licensed health care professional has determined, in the exercise of professional judgment, that the disclosure is reasonably likely to endanger the life or physical safety of the patient or another person, provided that, if required by applicable federal or state law, the patient has been afforded any right of review of that determination.

(b) If the practice implements an organizational policy, the policy must be—

(1) In writing;

(2) Based on relevant clinical, technical, and other appropriate expertise;

(3) Implemented in a consistent and non-discriminatory manner; and

(4) No broader than necessary to mitigate the risk of harm.

(c) If the practice does not implement an organizational policy, an actor must make a finding in each case, based on the particularized facts and circumstances, and based on, as applicable, relevant clinical, technical, and other appropriate expertise, that the practice is necessary and no broader than necessary to mitigate the risk of harm.

§ 171.202 Exception—Promoting the privacy of electronic health information.

To qualify for this exception, each practice by an actor must satisfy at least one of the sub-exceptions in paragraphs (b) through (e) of this section at all relevant times.

(a) *Meaning of ''individual'' in this section.* The term ''individual'' as used in this section means one or more of the following—

(1) An individual as defined by 45 CFR 160.103.

(2) Any other natural person who is the subject of the electronic health information being accessed, exchanged, or used.

(3) A person who legally acts on behalf of a person described in paragraph (a)(1) or (2) of this section, including as a personal representative, in accordance with 45 CFR 164.502(g).

(4) A person who is a legal representative of and can make health care decisions on behalf of any person described in paragraph (a)(1) or (2) of this section.

(5) An executor, administrator or other person having authority to act on behalf of a deceased person described in paragraph (a)(1) or (2) of this section or the individual's estate under State or other law.

(b) *Precondition not satisfied.* If the actor is required by a state or federal privacy law to satisfy a condition prior to providing access, exchange, or use of electronic health information, the actor may choose not to provide access, exchange, or use of such electronic health information if the precondition has not been satisfied, provided that—

(1) The actor's practice—

(i) Conforms to the actor's organizational policies and procedures that:

(A) Are in writing;

(B) Specify the criteria to be used by the actor and, as applicable, the steps that the actor will take, in order that the precondition can be satisfied; and

(C) Have been implemented, including by taking reasonable steps to ensure that its workforce members and its agents understand and consistently apply the policies and procedures; or

(ii) Has been documented by the actor, on a case-by-case basis, identifying the criteria used by the actor to determine when the precondition would be satisfied, any criteria that were not met, and the reason why the criteria were not met; and

(2) If the precondition relies on the provision of consent or authorization from an individual, the actor:

(i) Did all things reasonably necessary within its control to provide the individual with a meaningful opportunity to provide the consent or authorization; and

(ii) Did not improperly encourage or induce the individual to not provide the consent or authorization.

(3) The actor's practice is—

(i) Tailored to the specific privacy risk or interest being addressed; and

(ii) Implemented in a consistent and non-discriminatory manner.

(c) *Health IT developer of certified health IT not covered by HIPAA.* If the actor is a health IT developer of certified health IT that is not required to comply with the HIPAA Privacy Rule when engaging in a practice that promotes the privacy interests of an individual, the actor may choose not to provide access, exchange, or use of electronic health information provided that the actor's practice—

(1) Complies with applicable state or federal privacy laws;

(2) Implements a process that is described in the actor's organizational privacy policy;

(3) Had previously been meaningfully disclosed to the persons and entities that use the actor's product or service;

(4) Is tailored to the specific privacy risk or interest being addressed; and

(5) Is implemented in a consistent and non-discriminatory manner.

(d) *Denial of an individual's request for their electronic protected health information in the circumstances provided in 45 CFR 164.524(a)(1), (2), and (3).* If an individual requests their electronic protected health information under 45 CFR 164.502(a)(1)(i) or 45 CFR 164.524, the actor may deny the request in the circumstances provided in 45 CFR 164.524(a)(1), (2), or (3).

(e) *Respecting an individual's request not to share information.* In circumstances where not required or prohibited by law, an actor may choose not to provide access, exchange, or use of an individual's electronic health information if—

(1) The individual requests that the actor not provide such access, exchange, or use;

(2) Such request is initiated by the individual without any improper encouragement or inducement by the actor;

(3) The actor or its agent documents the request within a reasonable time period; and

(4) The actor's practice is implemented in a consistent and non-discriminatory manner.

§ 171.203 Exception—Promoting the security of electronic health information.

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) The practice must be directly related to safeguarding the confidentiality, integrity, and availability of electronic health information.

(b) The practice must be tailored to the specific security risk being addressed.

(c) The practice must be implemented in a consistent and non-discriminatory manner.

(d) If the practice implements an organizational security policy, the policy must—

(1) Be in writing;

(2) Have been prepared on the basis of, and directly respond to, security risks identified and assessed by or on behalf of the actor;

(3) Align with one or more applicable consensus-based standards or best practice guidance; and

(4) Provide objective timeframes and other parameters for identifying, responding to, and addressing security incidents.

(e) If the practice does not implement an organizational security policy, the actor must have made a determination in each case, based on the particularized facts and circumstances, that:

(1) The practice is necessary to mitigate the security risk to the electronic health information; and

(2) There are no reasonable and appropriate alternatives to the practice that address the security risk that are less likely to interfere with, prevent, or materially discourage access, exchange or use of electronic health information.

§ 171.204 Exception—Recovering costs reasonably incurred.

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Types of costs to which this exception applies.* This exception is limited to the actor's costs reasonably incurred to provide access, exchange, or use of electronic health information.

(b) *Method for recovering costs.* The method by which the actor recovers its costs—

(1) Must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests;

(2) Must be reasonably related to the actor's costs of providing the type of access, exchange, or use to, or at the request of, the person or entity to whom the fee is charged;

(3) Must be reasonably allocated among all customers to whom the technology or service is supplied, or for whom the technology is supported;

(4) Must not be based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the electronic health information in a way that facilitates competition with the actor; and

(5) Must not be based on the sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access to, exchange of, or use of electronic health information, including the secondary use of such information, that exceeds the actor's reasonable costs for providing access, exchange, or use of electronic health information.

(c) *Costs specifically excluded.* This exception does not apply to—

(1) Costs that the actor incurred due to the health IT being designed or implemented in non-standard ways that unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using electronic health information;

(2) Costs associated with intangible assets (including depreciation or loss of value), other than the actual development or acquisition costs of such assets;

(3) Opportunity costs, except for the reasonable forward-looking cost of capital;

(4) A fee prohibited by 45 CFR 164.524(c)(4);

(5) A fee based in any part on the electronic access by an individual or their personal representative, agent, or designee to the individual's electronic health information;

(6) A fee to perform an export of electronic health information via the capability of health IT certified to § 170.315(b)(10) of this subchapter for the purposes of switching health IT or to provide patients their electronic health information; or

(7) A fee to export or convert data from an EHR technology, unless such fee was agreed to in writing at the time the technology was acquired.

(d) *Compliance with the Conditions of Certification.* (1) Notwithstanding any other provision of this exception, if the actor is a health IT developer subject to the Conditions of Certification in § 170.402(a)(4) or § 170.404 of this subchapter, the actor must comply with all requirements of such conditions for all practices and at all relevant times.

(2) If the actor is an API Data Provider, the actor is only permitted to charge the same fees that an API Technology Supplier is permitted to charge to recover costs consistent with the permitted fees specified in the Condition of Certification in § 170.404 of this subchapter.

§ 171.205 Exception—Responding to requests that are infeasible.

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Request is infeasible.* (1) The actor must demonstrate, in accordance with

paragraph (a)(2) of this section, that complying with the request in the manner requested would impose a substantial burden on the actor that is unreasonable under the circumstances, taking into consideration—

(i) The type of electronic health information and the purposes for which it may be needed;

(ii) The cost to the actor of complying with the request in the manner requested;

(iii) The financial, technical, and other resources available to the actor;

(iv) Whether the actor provides comparable access, exchange, or use to itself or to its customers, suppliers, partners, and other persons with whom it has a business relationship;

(v) Whether the actor owns or has control over a predominant technology, platform, health information exchange, or health information network through which electronic health information is accessed or exchanged;

(vi) Whether the actor maintains electronic protected health information on behalf of a covered entity, as defined in 45 CFR 160.103, or maintains electronic health information on behalf of the requestor or another person whose access, exchange, or use of electronic health information will be enabled or facilitated by the actor's compliance with the request;

(vii) Whether the requestor and other relevant persons can reasonably access, exchange, or use the electronic health information from other sources or through other means; and

(viii) The additional cost and burden to the requestor and other relevant persons of relying on alternative means of access, exchange, or use.

(2) The following circumstances do not constitute a burden to the actor for purposes of this exception and shall not be considered in determining whether the actor has demonstrated that complying with a request would have been infeasible.

(i) Providing the requested access, exchange, or use in the manner requested would have facilitated competition with the actor.

(ii) Providing the requested access, exchange, or use in the manner requested would have prevented the actor from charging a fee.

(b) *Responding to requests.* The actor must timely respond to all requests relating to access, exchange, or use of electronic health information, including but not limited to requests to establish connections and to provide interoperability elements.

(c) *Written explanation.* The actor must provide the requestor with a detailed written explanation of the reasons why the actor cannot accommodate the request.

(d) *Provision of a reasonable alternative.* The actor must work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the electronic health information.

§ 171.206 Exception—Licensing of interoperability elements on reasonable and non-discriminatory terms.

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Responding to requests.* Upon receiving a request to license or use interoperability elements, the actor must respond to the requestor within 10 business days from receipt of the request by:

(1) Negotiating with the requestor in a reasonable and non-discriminatory fashion to identify the interoperability elements that are needed; and

(2) Offering an appropriate license with reasonable and non-discriminatory terms.

(b) *Reasonable and non-discriminatory terms.* The actor must license the interoperability elements described in paragraph (a) of this section on terms that are reasonable and non-discriminatory.

(1) *Scope of rights.* The license must provide all rights necessary to access and use the interoperability elements for the following purposes, as applicable.

(i) Developing products or services that are interoperable with the actor's health IT, health IT under the actor's control, or any third party who currently uses the actor's interoperability elements to interoperate with the actor's health IT or health IT under the actor's control.

(ii) Marketing, offering, and distributing the interoperable products and/or services to potential customers and users.

(iii) Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.

(2) *Reasonable royalty.* If the actor charges a royalty for the use of the interoperability elements described in paragraph (a) of this section, the royalty must be reasonable and comply with the following requirements.

(i) The royalty must be non-discriminatory, consistent with paragraph (b)(3) of this section.

(ii) The royalty must be based solely on the independent value of the actor's technology to the licensee's products, not on any strategic value stemming from the actor's control over essential means of accessing, exchanging, or using electronic health information.

(iii) If the actor has licensed the interoperability element through a standards development organization in accordance with such organization's policies regarding the licensing of standards-essential technologies on reasonable and non-discriminatory terms, the actor may charge a royalty that is consistent with such policies.

(3) *Non-discriminatory terms.* The terms (including royalty terms) on which the actor licenses and otherwise provides the interoperability elements must be non-discriminatory and comply with the following requirements.

(i) The terms must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests.

(ii) The terms must not be based in any part on—

(A) Whether the requestor or other person is a competitor, potential competitor, or will be using electronic health information obtained via the interoperability elements in a way that facilitates competition with the actor; or

(B) The revenue or other value the requestor may derive from access, exchange, or use of electronic health information obtained via the interoperability elements, including the secondary use of such electronic health information.

(4) *Collateral terms.* The actor must not require the licensee or its agents or contractors to do, or to agree to do, any of the following.

(i) Not compete with the actor in any product, service, or market.

(ii) Deal exclusively with the actor in any product, service, or market.

(iii) Obtain additional licenses, products, or services that are not related to or can be unbundled from the requested interoperability elements.

(iv) License, grant, assign, or transfer to the actor any intellectual property of the licensee.

(v) Pay a fee of any kind whatsoever, except as described in paragraph (b)(2) of this section, unless the practice meets the requirements of the exception in § 171.204.

(5) *Non-disclosure agreement.* The actor may require a reasonable non-disclosure agreement that is no broader than necessary to prevent unauthorized disclosure of the actor's trade secrets, provided—

(i) The agreement states with particularity all information the actor claims as trade secrets; and

(ii) Such information meets the definition of a trade secret under applicable law.

(c) *Additional requirements relating to the provision of interoperability elements.* The actor must not engage in any practice that has any of the following purposes or effects.

(1) Impeding the efficient use of the interoperability elements to access, exchange, or use electronic health information for any permissible purpose.

(2) Impeding the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand.

(3) Degrading the performance or interoperability of the licensee's products or services, unless necessary to improve the actor's technology and after affording the licensee a reasonable opportunity to update its technology to maintain interoperability.

(d) *Compliance with conditions of certification.* Notwithstanding any other provision of this exception, if the actor is a health IT developer subject to the conditions of certification in §§ 170.402, 170.403, or 170.404 of this subchapter, the actor must comply with all requirements of such conditions for all practices and at all relevant times.

§ 171.207 Exception—Maintaining and improving health IT performance.

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Maintenance and improvements to health IT.* An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the actor's practice is—

(1) For a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable;

(2) Implemented in a consistent and non-discriminatory manner; and

(3) If the unavailability is initiated by a health IT developer of certified health IT, HIE, or HIN, agreed to by the individual or entity to whom the health IT developer of certified health IT, HIE, or HIN supplied the health IT.

(b) *Practices that prevent harm.* If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a risk of harm to a patient or another person, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.201 at all relevant times to qualify for an exception.

(c) *Security-related practices.* If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a security risk to electronic health information, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.203 at all relevant times to qualify for an exception.

Dated: January 22, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix: Pediatric Technical Worksheets

These worksheets contain information on how each recommendation corresponds to the Children's EHR Format and to the existing or proposed new ONC certification criteria. We invite readers to use these worksheets to inform public comment on the recommendations, the inclusion of specific items from the Children's EHR Format,[193] and the identified certification criteria as they relate specifically to use cases for pediatric care and sites of service.

We welcome public comment on the identified certification criteria for each recommendation. Specifically, we seek comment for each recommendation on the following four broad questions:

- *Q1.* What relevant gaps, barriers, safety concerns, and/or resources (including available best practices, activities, and tools) may impact or support feasibility of the recommendation in practice?
- *Q2.* How can the effective use of IT support each recommendation as involves provider training, establishing workflow, and other related safety and usability considerations?
- *Q3.* Should any of the recommendations *not* be included?
- *Q4.* Should any of the functional criteria listed under the ''Alignment with 2015 Edition Certification Criteria'' and the ''Alignment with Proposed New or Updated Certification Criteria'' be removed as a correlated item to support any of the recommendations?

Commenters are encouraged to reference the specific recommendation number (110) with the corresponding question number in their response. For example, ''Recommendation 1. Q3.'' Commenters are highly encouraged to use the template ONC has created to support public comment on the proposed rule.

[193] *https://healthit.ahrq.gov/health-it-tools-and-resources/pediatric-resources/childrens-electronic-health-record-ehr-format.*

Recommendation 1: Use Biometric-Specific Norms for Growth Curves and Support Growth Charts for Children

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

Title: Use biometric-specific norms for growth curves.

Children's EHR Format: Req-2044—Release Package 2015 Priority List.

Topic(s): Primary Care Management, Well Child/Preventive Care.

Description: The system shall include the ability to use pediatric age-specific norms for weight, height/length, head circumference, and BMI to calculate and display growth percentiles and plot them over time on standardized Centers for Disease Control and Prevention/World Health Organizations (CDC/WHO) growth curves as appropriate.

Alignment With 2015 Edition Certification Criteria

ONC believes this recommendation is supported by the 2015 Edition definition and criteria listed below:

Common Clinical Data Set (CCDS)* including *optional* pediatric vital sign data elements with the reference range/scale or growth curve for BMI percentile per age and sex for youth 2–20 years of age, weight for age per length and sex for children less than three years of age, and head occipital-frontal circumference for children less than three years of age.

Demographic criterion requires the ability to record birth sex in accordance with HL7 Version 3 (''Administrative Gender'') and a null flavor value attributed as follows: Male (M); female (F); and unknown (UNK).

Clinical Decision Support (CDS) can be used to develop a variety of tools to enhance decision-making in the pediatric clinical workflow including contextually relevant reference information, clinical guidelines, condition-specific order sets, alerts, and reminders, among other tools.

Application Programming Interfaces criteria including the ''application access—patient selection'', ''application access—data category request'', and ''application access—all data request'' which can help address many of the challenges currently faced by caregivers accessing pediatric health data.

Alignment With Proposed New or Updated Certification Criteria

ONC believes this recommendation is supported by the proposed new and updated certification criteria in this proposed rule:

United States Core Data for Interoperability (USCDI): The USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference range/scale or growth curve for BMI percentile per age and sex, weight for age per length and sex, and head occipital-frontal circumference.

Application Programming Interfaces (APIs): § 170.315(g)(10), would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications to establish standardized application programming interfaces (APIs) for

interoperability purposes and to permit 3rd party software developers to connect to the electronic health record (EHR) through the certified API technology.

Supplemental Children's Format Requirements for Recommendation 1

We seek feedback about the relevance of the following potential supplemental Children's EHR Format requirements and their correlation to Recommendation 1.

1. *Title:* Allow unknown patient sex.
Children's EHR Format: Req-2009—Release Package 2015 Priority List.
Topic(s): Prenatal Screening, Birth Information, Genetic information.
Description: The system shall provide the ability to record a patient's sex as male, female, or unknown, and shall allow it to be updated.
2015 Edition Criterion Alignment: Demographics.
New or Updated Criterion Alignment: USCDI.

2. *Title:* Record Gestational Age Assessment and Persist in the EHR.
Children's EHR Format: Requirement Req-2019—Release Package 2015 Priority List.
Topic(s): Well Child/Preventive Care, Growth Data.
Description: The system shall capture and display assigned gestational age as well as the diagnosis of SGA (Small for Gestational Age) or LGA (Large for Gestational Age) when appropriate.
2015 Edition Criterion Alignment: Common Clinical Data Set (CCDS).
New or Updated Criterion Alignment: USCDI.

3. *Title:* Support growth charts for children.
Children's EHR Format: Requirement Req-2042—Release Package: 2015 Priority List.
Topic(s): Growth Data.
Description: The system shall support display of growth charts that plot selected growth parameters such as height, weight, head circumference, and BMI (entered with appropriate precision or computed as described in Req-2019) along with appropriate sets of norms provided by the CDC or in a compatible tabular format (typically based on Lambda-Mu-Sigma [LMS] curve fitting computational method).
2015 Edition Criterion Alignment: Common Clinical Data Set (CCDS), Clinical Decision Support (CDS).
New or Updated Criterion Alignment: USCDI, API.
Title: Provide alerts for out-of-range biometric data.
Children's EHR Format: Requirement Req-2045—Release Package 2015 Priority List.
Topic(s): Primary Care Management, Well Child/Preventive Care.
Description: The system shall include the ability to provide alerts for weight, length/height, head circumference, and BMI data points that fall outside two standard deviations of CDC/WHO pediatric data.
2015 Edition Criterion Alignment: Clinical Decision Support (CDS).
New or Updated Criterion Alignment: USCDI, API.

Recommendation 2: Compute Weight-Based Drug Dosage

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

Title: Compute weight-based drug dosage.
Children's EHR Format: Req-2012—Release Package 2015 Priority List.
Topic(s): Medication Management.
Description: The system shall compute drug dose, based on appropriate dosage ranges, using the patient's body weight and body surface area, and shall display the dosing weight and weight-based dosing strategy (when applicable) on the prescription.

Alignment With 2015 Edition Certification Criterion

ONC believes this recommendation is supported by the 2015 Edition criterion listed below:

- *Electronic Prescribing* criterion:

—Provides the ability to send and receive the specified prescription transactions electronically per the NCPDP SCRIPT Version 10.6 Standard Implementation Recommendations and using RxNorm vocabulary codes
—Limits the ability to prescribe all oral, liquid medications in only metric standard units of mL (*i.e.,* not cc)

Includes an *optional* Structured and Codified Sig Format, which has the capability to exchange weight-based dosing calculations within the NCPDP SCRIPT 10.6 standard.

Alignment With Proposed New or Updated Certification Criteria

ONC believes this recommendation is supported by the proposed new and updated certification criteria in this proposed rule:

- *United States Core Data for Interoperability (USCDI):* The USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference range/scale or growth curve for BMI percentile per age and sex, weight for age per length and sex, and head occipital-frontal circumference.
- *Electronic Prescribing:* (§ 170.315(b)(11)) which supports improved patient safety and prescription accuracy, workflow efficiencies, and increase configurability of systems including functionality that would support pediatric medication management.

Supplemental Children's Format Requirements for Recommendation 2

We seek feedback about the relevance of the following potential Children's EHR Format requirements and their correlation to Recommendation 2.

1. *Title:* Rounding for administrable doses.
Children's EHR Format: Req-2035—Release Package 2015 Priority List.
Topic(s): Medication Management.
Description: The system shall enable calculated doses (*e.g.,* weight-based) to be rounded to optimize administration convenience.
2015 Edition Criterion Alignment: Electronic prescribing.
New or Updated Criterion Alignment: Electronic prescribing.

2. *Title:* Alert based on age-specific norms.
Children's EHR Format: Req-2013—Release Package 2015 Priority List.
Topic(s): Primary Care Management, Well Child/Preventive Care.
Description: The system shall provide the ability to present alerts for lab results outside of pediatric-specific normal value ranges.
2015 Edition Criterion Alignment: Clinical decision support (CDS).
New or Updated Criterion Alignment: API.

Recommendation 3: Ability To Document All Guardians and Caregivers

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

Title: Ability to access family history, including all guardians and caregivers.
Children's EHR Format: Req-2006—Release Package 2015 Priority List.
Topic(s): Child Abuse Reporting, Primary Care Management, Parents and Guardians, and Family Relationship Data.
Description: The system shall provide the ability to record information about all guardians and caregivers (biological parents, foster parents, adoptive parents, guardians, surrogates, and custodians), siblings, and case workers, with contact information for each.

Alignment With 2015 Edition Certification Criteria

ONC believes this recommendation is supported by the 2015 Edition criteria listed below, and ONC believes this priority also is supported by health IT beyond what is included in the certification program.

- *Care Plan:* Criteria includes the ability to record, change, access, create, and receive care plan information according to the care plan document template in the HL7 implementation guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), draft standard for Trial Use Release 2.1 (including the sections for health status evaluations and outcomes and for interventions (V2)).
- *Transitions of Care:* Criteria includes the ability to create, receive, and properly consumer interoperable documents using a common content and transport standard that include key health data that should be accessible and available for exchange.
- *Application Programming Interfaces* criteria including the ''application access—patient selection'', ''application access—data category request'', and ''application access—all data request'' which can help address many of the challenges currently faced by caregivers accessing pediatric health data.
- *Transitions of Care* criteria includes the ability to create and to receive interoperable documents using a comment content standard that include key health data that should be accessible and available for exchange to support the care of children across care settings.
- *Demographic* criterion requires the ability to record various demographic information for a patient including potential supports for patient and parental matching.

Alignment With Proposed New or Updated Certification Criteria

ONC believes tis priority is supported by the proposed new and updated certification criteria in this proposed rule:

• *United States Core Data for Interoperability (USCDI):* The USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference range/scale or growth curve for BMI percentile per age and sex, weight for age per length and sex, and head occipital-frontal circumference.

• *Data Segmentation for Privacy:* (two for C–CDA ((§ 170.315(b)(12)) and (§ 170.315(b)(13)) and one for FHIR (§ 170.315(g)(11))) could provide functionality to address the concerns multiple stakeholders expressed regarding the need to restrict granular pediatric health data at production based on the intended recipient of the data.

• *Application Programming Interfaces (APIs):* § 170.315(g)(10), would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications to establish standardized application programming interfaces (APIs) for interoperability purposes and to permit 3rd party software developers to connect to the electronic health record (EHR) through the certified API technology.

Supplemental Children's EHR Format Requirements for Recommendation 3

We seek feedback about the relevance of the following potential supplemental Children's EHR Format requirements and their correlation to Recommendation 3.

1. *Title:* Ability to document parental (guardian) notification or permission.

Children's EHR Format: Req-2008: Release Package: 2015 Priority List.

Topic(s): Security and Confidentiality, Parents and Guardians, and Family Relationship Data.

Description: The system shall provide the ability to document parental (guardian) notification or permission for consenting minors to receive some treatments as required by institutional policy or jurisdictional law.

2015 Edition Criterion Alignment: Data segmentation for privacy—send criterion, data segmentation for privacy—receive criterion, and/or the patient health information capture criterion, view, download, and transmit (VDT) to third-party, and Application Programming Interface (API).

New or Updated Criterion Alignment: Data segmentation for privacy.

2. *Title:* Record parental notification of newborn screening diagnosis.

Children's EHR Format: Req-2016: Release Package: 2015 Priority List.

Topic(s): Newborn Screening.

Description: The system shall be able to track that the child's legal guardians were notified of any newborn screening-related diagnosis.

2015 Edition Criterion Alignment: Question: View, download, and transmit (VDT) to third-party, secure messaging, Application Programming Interface (API).

New or Updated Criterion Alignment: API.

3. *Title:* Authorized non-clinician viewers of EHR data.

Children's EHR Format: Req-2032—Release Package 2015 Priority List.

Topic(s): Child Welfare, Patient Portals (PHR).

Description: The system shall have the ability to identify members of the care team (including professional and nonprofessional members) and indicate their roles/relationships to the child.

2015 Edition Criterion Alignment: Care plan criterion, authentication, access control, and authorization.

New or Updated Criterion Alignment: API.

4. *Title:* Document decision-making authority of patient representative.

Children's EHR Format: Req-2030: Release Package: 2015 Priority List.

Topic(s): Security and Confidentiality.

Description: The system shall have the ability to store, retrieve, and display information about an individual's right to authorize care, to release information, and to authorize payment for care on behalf of the patient, including time restrictions or other limitations. This includes storing copies of the relevant consent and authorization forms in compliance with state and federal rules, and also includes cases of child foster care, state social services agencies, guardians, guarantors, and those recognized to have full or partial authority. The system shall allow for multiple individuals.

2015 Edition Criterion Alignment: Patient health information capture.

New or Updated Criterion Alignment: Data segmentation.

Recommendation 4: Segmented Access to Information

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

Title: Segmented access to information.

Children's EHR Format: Req-2041: Release Package: 2015 Priority List.

Topic(s): Security and Confidentiality.

Description: The system shall provide users the ability to segment health care data in order to keep information about minor consent services private and distinct from other content of the record, such that it is not exposed to parents/guardians without the minor's authorization.

Alignment With 2015 Edition Certification Criteria

ONC believes this recommendation is supported by the 2015 Edition Criteria listed below, and ONC believes this recommendation is supported by health IT beyond what is included in the certification program

• *Data Segmentation for Privacy* criteria:

○ Data segmentation for privacy—send criterion provides the ability to create a summary record (formatted to Consolidated CDA (C–CDA) Release 2.1) that is tagged at the document level as restricted and subject to re-disclosure restrictions using the HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1.

○ Data segmentation for privacy—receive criterion requires the ability to receive a summary record (formatted to Consolidated CDA Release 2.1) that is document—level tagged as restricted and subject to re-disclosure restrictions using the HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1. Requires the ability to separate the document-level tagged document from other documents received. Requires the ability to view the restricted document without having to incorporate any of the data from the document.

• *Transitions of Care* criteria includes the ability to create, receive, and properly consumer interoperable documents using a common content and transport standard that include key health data that should be accessible and available for exchange.

Alignment With Proposed New or Updated Certification Criteria

ONC believes this recommendation is supported by the proposed new and updated certification criteria in this proposed rule:

• *United States Core Data for Interoperability (USCDI):* The USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference range/scale or growth curve for BMI percentile per age and sex, weight for age per length and sex, and head occipital-frontal circumference.

• *Data Segmentation for Privacy:* (two for C–CDA ((§ 170.315(b)(12)) and (§ 170.315(b)(13)) and one for FHIR (§ 170.315(g)(11))) would provide functionality to address the concerns multiple stakeholders expressed regarding the need to restrict granular pediatric health data at production based on the intended recipient of the data.

• *Application Programming Interfaces (APIs):* § 170.315(g)(10), would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications to establish standardized application programming interfaces (APIs) for interoperability purposes and to permit 3rd party software developers to connect to the electronic health record (EHR) through the certified API technology.

Supplemental Children's Format Requirements for Recommendation 4

We seek feedback about the relevance of the following potential Children's EHR Format requirements and their correlation to Recommendation 4.

1. *Title:* Problem-specific age of consent.

Children's EHR Format: Req-2039: Release Package: 2015 Priority List.

Topic(s): Security and Confidentiality.

Description: The system shall provide the ability to access legal guidelines on consent requirements for reference, where available, and to record the age of consent for a specific treatment when these differ based on legal guidelines.

2015 Edition Criterion Alignment: Demographics, care plan criterion, data segmentation for privacy—send, data segmentation for privacy—receive.

New or Updated Criterion Alignment: USCDI, data segmentation.

Recommendation 5: Synchronize Immunization Histories With Registries

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

Title: Synchronize immunization histories with registry.

Children's EHR Format: Req-2011*: Release Package: 2015 Priority List.

Topic(s): Registry Linkages, Immunizations.

Description: The system shall support updating and reconciling a child's immunization record with information received from immunization information systems or other health information exchanges (HIEs).

Title: Use established immunization messaging standards.

Children's EHR Format: Req-2028 Release Package: 2015 Priority List.

Topic(s): Registry Linkages, Immunizations.

Description: (A) The system shall use the messaging standards established through meaningful use requirements to send data to immunization information systems or other HIEs. (B) The system shall use the messaging standards established through meaningful use requirements to receive data from immunization information systems or other HIEs.

Alignment With 2015 Edition Certification Criterion

ONC believes this recommendation is supported by the 2015 Edition Criterion listed below:

- *Transmission to Immunization Registries* criterion, which:
  - ○ Provides the ability to create immunization information according to the implementation guide for Immunization Messaging Release 1.5, and the July 2015 addendum, using CVX codes for historical vaccines and NDC codes for newly administered vaccines.
  - ○ Provides the ability to request, access, and display the evaluated immunization history and forecast from an immunization registry for a patient in accordance with the HL7 2.5.1 standard, the HL7 2.5.1. IG for Immunization Messaging, Release 1.5, and July 2015 addendum.
- *View, Download, and Transmit to Third Party (VDT)* criterion, which:
  - ○ Provides the ability for patients (and their authorized representatives) to view, download, and transmit their health information to a third party via internet-based technology consistent with one of the Web Content Accessibility Guidelines (WCAG) 2.0 Levels A or AA.
  - ○ Requires the ability for patients (and their authorized representatives) to view, at a minimum, the Common Clinical Data Set, laboratory test report(s), and diagnostic image reports.

Alignment With Proposed New or Updated Certification Criteria

- *United States Core Data for Interoperability (USCDI):* The USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference range/scale or growth curve for BMI percentile per age and sex, weight for age per length and sex, and head occipital-frontal circumference.
- *Application Programming Interfaces (APIs):* § 170.315(g)(10), would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications to establish standardized application programming interfaces (APIs) for interoperability purposes and to permit 3rd party software developers to connect to the electronic health record (EHR) through the certified API technology.

Supplemental Children's Format Requirements for Recommendation 5

We seek feedback about the relevance of the following potential Children's EHR Format requirements and their correlation to Recommendation 5.

1. *Title:* Produce completed forms from EHR data.

The Children's EHR Format: Req-2027 Release Package: 2015 Priority List.

Topic(s): Well Child/Preventive Care, Immunizations.

Description: The system shall produce reports (*e.g.,* for camp, school, or child care) of a child's immunization history, including the following elements: Child's name, date of birth and sex, date the report was produced, antigen administered, date administered, route of administration (when available), and an indication of whether a vaccine was refused or contraindicated.

2015 Edition Certification Alignment: Transmission to immunization registries, View, Download and Transmit (VDT), Application Programming Interface (API).

New or Updated Criterion Alignment: API.

Recommendation 6: Age- and Weight-Specific Single-Dose Range Checking

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirements as follows:

Title: Age- and weight-specific single-dose range checking.

Children's EHR Format: Req-2037: Release Package: 2015 Priority List.

Topic(s): Medication Management.

Description: The system shall provide medication dosing decision support that detects a drug dose that falls outside the minimum-maximum range based on the patient's age, weight, and maximum recommended adult dose (if known) or maximum recommended pediatric dose (if known), for a single dose of the medication.

Alignment With 2015 Edition Certification Criteria

ONC believes this recommendation is supported by the 2015 Edition criterion listed below:

Clinical Decision Support (CDS) can be used to develop a variety of tools to enhance decision-making in the pediatric clinical workflow including contextually relevant reference information, clinical guidelines, condition-specific order sets, alerts, and reminders, among other tools.

Application Programming Interfaces criteria including the ''application access—patient selection'', ''application access—data category request'', and ''application access—all data request'' which can help address many of the challenges currently faced by caregivers accessing pediatric health data.

ONC believes this priority could also be supported by health IT beyond what is included in the certification program.

ONC notes that per the National Council for Prescription Drug Programs (NCPDP), dose-range checking should be based on industry drug database products and are not intrinsic to SCRIPT.

Alignment With Proposed New or Updated Certification Criteria

- *United States Core Data for Interoperability (USCDI):* The USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference range/scale or growth curve for BMI percentile per age and sex, weight for age per length and sex, and head occipital-frontal circumference.
- *Application Programming Interfaces (APIs):* § 170.315(g)(10), would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications to establish standardized application programming interfaces (APIs) for interoperability purposes and to permit 3rd party software developers to connect to the electronic health record (EHR) through the certified API technology.

Recommendation 7: Transferrable Access Authority

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

Title: Transferrable access authority.

Children's EHR Format: Req-2026: Release Package: 2015 Priority List.

Topic(s): School-Based Linkages, Security and Confidentiality, Patient Portals and Patient Health Records (PHR).

Description: The system shall provide a mechanism to enable access control that allows a transferrable access authority (*e.g.,* to address change in guardian, child reaching age of maturity, etc.).

Alignment With 2015 Edition Certification Criterion

ONC believes this recommendation is supported by the 2015 Edition criterion below.

- *View, Download, and Transmit to Third Party (VDT)* criterion, which:
  - ○ Provides the ability for patients (and their authorized representatives) to view, download, and transmit their health information to a third party via internet-based technology consistent with one of the Web Content Accessibility Guidelines (WCAG) 2.0 Levels A or AA.
  - ○ Requires the ability for patients (and their authorized representatives) to view, at a minimum, the Common Clinical Data Set, laboratory test report(s), and diagnostic image reports.

Application Programming Interfaces criteria including the ''application access—patient selection'', ''application access—data

category request'', and ''application access—all data request'' which can help address many of the challenges currently faced by caregivers accessing pediatric health data.

Alignment With Proposed New or Updated Certification Criterion

• *Data Segmentation for Privacy:* (two for C–CDA ((§ 170.315(b)(12)) and (§ 170.315(b)(13)) and one for FHIR (§ 170.315(g)(11))) would provide functionality to address the concerns multiple stakeholders expressed regarding the need to restrict granular pediatric health data at production based on the intended recipient of the data.

• *Application Programming Interfaces (APIs):* § 170.315(g)(10), would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications to establish standardized application programming interfaces (APIs) for interoperability purposes and to permit 3rd party software developers to connect to the electronic health record (EHR) through the certified API technology.

Supplemental Children's Format Requirements for Recommendation 7

We seek feedback about the relevance of the following potential Children's EHR Format requirements and their correlation to Recommendation 7.

1. *Title:* Age of emancipation.

The Children's EHR Format: Requirement Req-2040 Release Package: 2015 Priority List.

Topic(s): Security and Confidentiality.

Description: The system shall provide the ability to record the patient's emancipated minor status.

2015 Edition Criterion Alignment: Demographic.

New or Updated Criterion Alignment: Data segmentation.

Recommendation 8: Associate Maternal Health Information and Demographics With Newborn

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

Title: Associate mother's demographics with newborn.

Children's EHR Format: Req-2021: Release Package: 2015 Priority List

Topic(s): Patient Identifier, Parents and Guardians and Family Relationship Data.

Description: The system shall provide the ability to associate identifying parent or guardian demographic information, such as relationship to child, street address, telephone number, and/or email address for each individual child.

Alignment With the 2015 Edition Certification Criterion

ONC believes this recommendation is supported by the 2015 Edition criterion below:

• *Care Plan:* Criteria includes the ability to record, change, access, create, and receive care plan information according to the care plan document template in the HL7 implementation guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), draft standard for Trial Use Release 2.1 (including the sections for health status evaluations and outcomes and for interventions (V2)).

• *Transitions of Care* criteria includes the ability to create and to receive interoperable documents using a comment content standard that include key health data that should be accessible and available for exchange to support the care of children across care settings.

• *Demographic* criterion requires the ability to record various demographic information for a patient including potential supports for patient and parental matching.

• *Family Health History* criterion permits the ability to record, change, and access a patient's family health history (according to the September 2015 release of SNOMED CT®, U.S. edition).

• *Social, Psychological, and Behavioral Data* criteria capture information (also known as social determinants of health) that can help to provide a more complete view of a mother's overall health status.

Alignment With Proposed New or Updated Certification Criteria

• *United States Core Data for Interoperability (USCDI):* The USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference range/scale or growth curve for BMI percentile per age and sex, weight for age per length and sex, and head occipital-frontal circumference.

• *Application Programming Interfaces (APIs):* § 170.315(g)(10), would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications to establish standardized application programming interfaces (APIs) for interoperability purposes and to permit 3rd party software developers to connect to the electronic health record (EHR) through the certified API technology.

Recommendation 9: Track Incomplete Preventative Care Opportunities

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

Title: Track incomplete preventive care opportunities.

Children's EHR Format: Req-2024: Release Package: 2015 Priority List.

Topic(s): Well Child/Preventive Care.

Description: The system shall generate a list on demand for any children who have missed recommended health supervision visits (*e.g.,* preventive opportunities), according to the frequency of visits recommended in Bright Futures™.

Alignment With 2015 Edition Certification Criteria

ONC believes this recommendation is supported by the 2015 Edition criterion below:

Clinical Decision Support (CDS) criterion includes configuration that enables interventions based on various CCDS data elements, including vital signs.

• *Clinical Quality Measures* criteria for record and export, import and calculate, and filter criteria:

○ Record and export criterion ensures that health IT systems can record and export CQM data electronically; the export functionality gives clinicians the ability to export their results to multiple programs.

○ import and calculate criterion supports streamlined clinician processes through the importing of CQM data in a standardized format and ensures that health IT systems can correctly calculate eCQM results using a standardized format.

○ filter criterion supports the capability for a clinician to make a query for eCQM results using or a combination of data captured by the certified health IT for quality improvement and quality reporting purposes.

• *Application Programming Interfaces* criteria including the ''application access—patient selection'', ''application access—data category request'', and ''application access—all data request'' which can help address many of the challenges currently faced by caregivers accessing pediatric health data.

Alignment With Proposed New or Updated Certification Criteria

ONC believes this recommendation is supported by the proposed new and updated certification criteria in this proposed rule:

• *Application Programming Interfaces (APIs):* § 170.315(g)(10), would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications to establish standardized application programming interfaces (APIs) for interoperability purposes and to permit 3rd party software developers to connect to the electronic health record (EHR) through the certified API technology.

Recommendation 10: Flag Special Health Care Needs

Alignment With Children's EHR Format

Stakeholders identified alignment with the Children's EHR Format Requirement as follows:

Title: Flag special health care needs.

The Children's EHR Format: Req-2014: Release Package: 2015 Priority List.

Topic(s): Children with Special Health Care Needs.

Description: The system shall support the ability for providers to flag or un-flag individuals with special health care needs or complex conditions who may benefit from care management, decision support, and care planning, and shall support reporting.

Alignment With 2015 Edition Certification Criteria

ONC believes this recommendation is supported by the 2015 Edition criterion below.

• *Problem List* criterion contains the patient's current health problems, injuries, chronic conditions, and other factors that affect the overall health and well-being of the patient.

• *Clinical Decision Support (CDS)* can be used to develop a variety of tools to enhance decision-making in the pediatric clinical workflow including contextually relevant

reference information, clinical guidelines, condition-specific order sets, alerts, and reminders, among other tools.

• *Clinical Quality Measures* criteria for record and export, import and calculate, and filter criteria:

○ Record and export criterion ensures that health IT systems can record and export CQM data electronically; the export functionality gives clinicians the ability to export their results to multiple programs.

○ import and calculate criterion supports streamlined clinician processes through the importing of CQM data in a standardized format and ensures that health IT systems can correctly calculate eCQM results using a standardized format.

○ filter criterion supports the capability for a clinician to make a query for eCQM results using or a combination of data captured by the certified health IT for quality improvement and quality reporting purposes.

Alignment With Proposed New or Updated Certification Criteria

ONC believes this recommendation is supported by the proposed new and updated certification criteria in this proposed rule:

• *United States Core Data for Interoperability (USCDI):* The USCDI (§ 170.213) which enables the inclusion of pediatric vital sign data elements, including the reference range/scale or growth curve for BMI percentile per age and sex, weight for age per length and sex, and head occipital-frontal circumference.

• *Application Programming Interfaces (APIs):* § 170.315(g)(10), would require the use of Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standards and several implementation specifications to establish standardized application programming interfaces (APIs) for interoperability purposes and to permit 3rd party software developers to connect to the electronic health record (EHR) through the certified API technology.

[FR Doc. 2019–02224 Filed 2–22–19; 4:15 pm]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 406, 407, 422, 423, 431, 438, 457, 482, and 485

Office of the Secretary

45 CFR Part 156

[CMS–9115–P]

RIN 0938–AT79

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule is intended to move the health care ecosystem in the direction of interoperability, and to signal our commitment to the vision set out in the 21st Century Cures Act and Executive Order 13813 to improve access to, and the quality of, information that Americans need to make informed health care decisions, including data about health care prices and outcomes, while minimizing reporting burdens on affected plans, health care providers, or payers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 3, 2019.

ADDRESSES: In commenting, please refer to file code CMS–9115–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9115–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9115–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Alexandra Mugge, (410) 786–4457, for issues related to interoperability, CMS health IT strategy, technical standards and patient matching.

Natalie Albright, (410) 786–1671, for issues related to Medicare Advantage.

John Giles, (410) 786–1255, for issues related to Medicaid.

Emily Pedneau, (301) 492–4448, for issues related to Qualified Health Plans.

Meg Barry, (410) 786–1536, for issues related to CHIP.

Thomas Novak, (202) 322–7235, for issues related to trust exchange networks and payer to payer coordination.

Sharon Donovan, (410) 786–9187, for issues related to federal-state data exchange.

Daniel Riner, (410) 786–0237, for issues related to Physician Compare.

Ashley Hain, (410) 786–7603, for issues related to hospital public reporting.

Melissa Singer, (410) 786–0365, for issues related to provider directories.

CAPT Scott Cooper, USPHS, (410) 786–9465, for issues related to hospital and critical access hospital conditions of participation.

Lisa Bari, (410) 786–0087, for issues related to advancing interoperability in innovative models.

Russell Hendel, (410) 786–0329, for issues related to the Collection of Information or the Regulation Impact Analysis sections.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background and Summary of Provisions

A. Purpose

This proposed rule is the first phase of proposed policies centrally focused on advancing interoperability and patient access to health information using the authority available to the Centers for Medicare & Medicaid Services (CMS). We believe this is an important step in advancing interoperability, putting patients at the center of their health care and ensuring they have access to their health information. We are committed to solving the issue of interoperability and achieving complete access to health information for patients in the United States (U.S.) health care system, and are taking an active approach to move participants in the health care market toward interoperability and the secure and timely exchange of health information by proposing and adopting policies for the Medicare and Medicaid programs, the Children's Health Insurance Program (CHIP), and issuers of qualified health plans (QHPs).

Throughout this proposed rule, we refer to terms such as patient, consumer, beneficiary, enrollee, and individual. We note that every reader of this proposed rule is a patient and has or will receive medical care at some point in their life. In this proposed rule, we use the term ''patient'' as an inclusive term, but because we have historically referred to patients using other terms in our regulations, we use specific terms as applicable in sections of this proposed rule to refer to individuals covered under the health care programs that CMS administers and regulates. We also use terms such as payer, plan, and issuer in this proposed rule. Certain portions of this proposed rule are applicable to the Medicare Fee-for-Service (FFS) Program, the Medicaid FFS Program, the CHIP FFS program, Medicare Advantage (MA) Organizations, Medicaid Managed Care plans (managed care organizations (MCOs), prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs)), CHIP Managed Care entities (MCOs, PIHPs, and PAHPs), and QHP issuers in Federally-facilitated Exchanges (FFEs). We use the term ''payer'' as an inclusive term, but we use specific terms as applicable in sections of this proposed rule.

B. Overview

We are dedicated to enhancing and protecting the health and well-being of all Americans. One critical issue in the U.S. health care system is that people cannot easily access their complete health information in interoperable forms. Patients and the health care providers caring for them are often presented with an incomplete picture of their health and care as pieces of their information are stored in various, unconnected systems and do not accompany the patient to every care setting.

We believe patients should have the ability to move from health plan to health plan, provider to provider, and have both their clinical and administrative information travel with them throughout their journey. When a patient receives care from a new provider, a complete record of their health information should be readily available to that care provider, regardless of where or by who care was previously provided. When a patient is discharged from a hospital to a post-acute care (PAC) setting there should be no question as to how, when, or where their data will be exchanged. Likewise, when an enrollee changes health plans or ages into Medicare, the enrollee should be able to have their claims history and encounter data follow so that information is not lost.

For providers in clinical settings, health information technology (health IT) should be a resource, designed to make it faster and easier for providers to deliver high quality care, creating efficiencies and allowing them to access all available data for their patients. Health IT should not detract from the clinician-patient relationship, from the patient's experience of care, or from the quality of work life for physicians, nurses, and other health care professionals. Through standards-based interoperability and exchange, health IT has the potential to be a resource and facilitator for efficient, safe, high-quality care for individuals and populations.

All payers, including health plans, should have the ability to exchange data seamlessly with other payers for timely benefits coordination or transitions, and with providers to facilitate more coordinated and efficient care. Health plans are in a unique position to provide enrollees a complete picture of their claims and encounter data, allowing patients to piece together their own information that might otherwise be lost in disparate systems. This information can contribute to better informed decision making, helping to inform the patient's choice of coverage options and care providers to more effectively manage their own health, care, and costs.

We are committed to solving the issue of interoperability and patient access in the U.S. health care system while reducing administrative burdens on providers and are taking an active approach using all available policy levers and authorities to move participants in the health care market toward interoperability and the secure and timely exchange of health care information.

C. Executive Order and MyHealthEData

On October 12, 2017, President Trump issued Executive Order 13813 to Promote Healthcare Choice and Competition Across the United States. Section 1(c)(iii) of Executive Order 13813 states that the Administration will improve access to, and the quality of, information that Americans need to make informed health care decisions, including information about health care prices and outcomes, while minimizing reporting burdens on affected plans, providers, and payers.

In support of Executive Order 13813, the Administration launched the MyHealthEData initiative. This government-wide initiative aims to empower patients by ensuring that they have full access to their own health information and the ability to decide how their data will be used, while keeping that information safe and secure. MyHealthEData aims to break down the barriers that prevent patients from gaining electronic access to their health information from the device or application of their choice, empowering patients and taking a critical step toward interoperability and patient data exchange.

In March 2018, the White House Office of American Innovation and the CMS Administrator announced the launch of MyHealthEData, and CMS's direct, hands-on role in improving patient access and advancing interoperability. As part of the MyHealthEData initiative, we are taking a patient-centered approach to health information access and moving to a system in which patients have immediate access to their computable health information and can be assured that their health information will follow them as they move throughout the health care system from provider to provider, payer to payer. To accomplish this, we have launched several initiatives related to data sharing and interoperability to empower patients and encourage plan and provider competition. In this proposed rule, we continue to advance the policies and goals of the MyHealthEData initiative through various proposals as outlined in the following sections.

Our proposals are wide-reaching and would have an impact on all facets of the health care system. Several key

touch points of the proposals in this rule include:

• *Patients:* Enabling patients to access their health information electronically without special effort by requiring the payers subject to this proposed rule to make the data available through an application programming interface (API) to which third party software applications connect to make the data available to patients. This encourages them to take charge of and better manage their health care, and thus these initiatives are imperative to improving a patient's long-term health outcomes.

• *Clinicians and Hospitals:* Ensuring that health care providers have ready access to health information about their patients, regardless of where the patient may have previously received care. We are also proposing policies to prevent health care providers from inappropriately restricting the flow of information to other health care providers and payers. Finally, we are working to ensure that better interoperability reduces the burden on health care providers.

• *Payers:* Proposing requirements to ensure that payers (that is, entities and organizations that pay for health care), such as MA plans and Medicaid and CHIP programs, make enrollee electronic health information held by the plan available through an API such that, with use of software we expect payers and third parties to develop, the information becomes easily accessible to the enrollee, and that the data flows seamlessly with the enrollee as they change providers, plans, and issuers. Additionally, our proposals would ensure that payers make it easy for current and prospective enrollees to identify which providers are within a given plan's network in a way that is simple and easy for enrollees to access and understand, and thus find the providers that are right for them.

Under our proposals to standardize data and technical approaches to advance interoperability, we believe health care providers and their patients, as well as other key participants within the health care ecosystem such as plans and payers, will have appropriate access to the information necessary to coordinate individual care, analyze population health trends, outcomes, and costs, and manage benefits and the health of populations, while tracking progress through quality improvement initiatives. We are working with other federal partners including the Office of the National Coordinator for Health Information Technology (ONC) on this effort with the clear objective to improve patient access and care, alleviate provider burden, and reduce overall health care costs.

D. Past Efforts

The Department of Health and Human Services (HHS) has been working to advance the interoperability of electronic health information since 2004, when the ONC was initially created via Executive Order 13335. From 2004 to 2009, ONC worked with a variety of federal and private sector stakeholders to coordinate private and public actions, began harmonizing data standards, and worked to advance nationwide health information exchange. In 2009, the National Coordinator position, office, and statutory duties were codified by the Health Information Technology for Economic and Clinical Health Act (HITECH Act), enacted as part of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5, enacted February 17, 2009), at Title 42—Health Information Technology and Quality (42 U.S.C. 300jj *et seq.*) of the Public Health Service Act (PHSA). Under section 3001(c)(5) of the PHSA, ONC established a voluntary certification program to certify that health IT met standards, implementation specifications, and certification criteria adopted by the Secretary. ONC is organizationally located within HHS' Office of the Secretary and is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health IT and the electronic exchange of health information.

The HITECH Act provided the opportunity to move interoperability forward in many additional meaningful ways. A few are particularly worth noting in relation to this proposed rule. For instance, HITECH also amended the Social Security Act (the Act), authorizing CMS to make incentive payments (and in later years, make downward adjustments to Medicare payments) to eligible professionals, eligible hospitals and critical access hospitals (CAHs), and MA organizations to promote the adoption and meaningful use of certified electronic health record technology (CEHRT). In 2010, through rulemaking, we established criteria for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs to encourage eligible professionals, eligible hospitals, and CAHs to adopt, implement, upgrade, and demonstrate the meaningful use of CEHRT. The programs were implemented in three stages:

• Stage 1 set the foundation for the EHR Incentive Programs by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of health information.

• Stage 2 expanded upon the Stage 1 criteria with a focus on advancing clinical processes and ensuring that the meaningful use of EHRs supported the aims and priorities of the National Quality Strategy. Stage 2 criteria encouraged the use of CEHRT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible.

• Stage 3 focuses on using CEHRT to improve health outcomes.

The federal government has spent over $35 billion under the EHR Incentive Programs to incentivize the adoption and meaningful use of EHR systems by eligible professionals, eligible hospitals, and CAHs; however, despite the fact that 78 percent of physicians [1] and 96 percent of hospitals [2] now use a certified EHR system, progress on system-wide data sharing has been limited.

In 2010, under the HITECH Act, ONC adopted an initial set of standards, implementation specifications, and certification criteria, and established the Temporary Certification Program for Health Information Technology, under which health IT developers could begin to obtain certification of the EHR technology that eligible professionals, eligible hospitals, and CAHs would need to adopt and use to satisfy CMS Stage 1 requirements for demonstration of meaningful use of CEHRT. In January 2011, ONC replaced the Temporary Certification Program with the Permanent Certification Program for Health Information Technology (45 CFR part 170). The Secretary has adopted iterative editions of the set of standards, implementation specifications, and certification criteria included in the Programs to keep pace with advances in standards, health information exchange, and the health IT market. In addition, this helps to maintain alignment with the needs of health care providers seeking to succeed within health IT-linked federal programs.

In April 2015, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015), which declared it a national

[1] ONC, *Health IT Dashboard,* ''Office-based Physician Health IT Adoption: State rates of physician EHR adoption, health information exchange & interoperability, and patient engagement (2015),'' *https://dashboard.healthit.gov/apps/physician-health-it-adoption.php* (last accessed July 9, 2018).

[2] ONC, *Health IT Dashboard,* ''Non-federal Acute Care Hospital Health IT Adoption and Use: State rates of non-federal acute care hospital EHR adoption, health information exchange and interoperability, and patient engagement (2015),'' *https://dashboard.healthit.gov/apps/hospital-health-it-adoption.php* (last accessed July 9, 2018).

objective to achieve widespread exchange of health information through interoperable CEHRT nationwide. Section 106(b)(1)(B)(ii) of MACRA defines ''interoperability'' as the ability of two or more health information systems or components to exchange clinical and other information and to use the information that has been exchanged using common standards as to provide access to longitudinal information for health care providers in order to facilitate coordinated care and improved patient outcomes. The MACRA charges the Secretary to establish metrics to be used to determine if widespread interoperability had been achieved, and the heading of section 106(b)(2) of the MACRA refers to ''preventing blocking the sharing of information.'' Specifically, section 106(b)(2) of the MACRA amended section 1848(o)(2)(A)(ii) of the Act for eligible professionals and section 1886(n)(3)(A)(ii) of the Act for eligible hospitals and CAHs to require that the professional or hospital demonstrate that they have not knowingly and willfully taken action to limit or restrict the compatibility or interoperability of CEHRT. For a discussion of the attestation requirements that we established and codified to support the prevention of information blocking, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77028 through 77035).

In April 2018, we renamed the EHR Incentive Programs and the MIPS Advancing Care Information performance category to the Promoting Interoperability (PI) Programs and Promoting Interoperability performance category, respectively (83 FR 41635). This refocusing and rebranding of the initiatives is just one part of the CMS strategic shift in focus to advancing health IT and interoperability.

CMS appreciates the pathways Congress opened for action on interoperability, as will be discussed in more detail throughout this proposed rule and has been working diligently with ONC to support implementation. In addition, in order to make sure we have as much stakeholder feedback on all the options CMS specifically has available to best take advantage of this new opportunity to promote interoperability, over a span of several months in 2018, we released interoperability Requests for Information (RFIs) in several Medicare payment rules, including in the FY 2019 Inpatient Prospective Payment System (IPPS) proposed rule (83 FR 20164). While the Interoperability RFI in the FY 2019 IPPS proposed rule was focused primarily on how and whether changes to Hospital Conditions of Participation and other like program requirements could impact or contribute to advancing interoperability, stakeholders provided additional input that we are taking under advisement for the purposes of advancing interoperability generally in this proposed rule. For example, some commenters recommended aligning existing standards and adopting common standards and/or data elements across the health care industry as a whole (not just focusing on providers), incentivizing the use of standards, and removing barriers as possible ways to address gaps in interoperability. Commenters also expressed support for the use of open APIs but cautioned CMS to consider the need to ensure health information security. Support was also expressed for enhancing applications that are designed for patient, or consumer use, such as Blue Button 2.0 (CMS' Medicare FFS open API for patient access to health information), and the development of patient-facing consumer applications that aggregate various longitudinal health information for the patient into one location. We plan to continue to review the public comments we receive to help identify opportunities for CMS to advance interoperability in future rulemaking and subregulatory guidance.

CMS is also working with partners in the private sector to promote interoperability. In 2018, CMS began participating in the Da Vinci project, a private-sector initiative led by Health Level 7 (HL7), a standards development organization. For one of the use cases under this project—called ''Coverage Requirements and Documentation Rules Discovery''—the Da Vinci project developed a draft Fast Healthcare Interoperability Resources (FHIR) standard during the summer and fall of 2018. In June 2018, in support of the Da Vinci project, the CMS Medicare FFS program began: (1) Developing a prototype Documentation Requirement Lookup Service for the Medicare FFS program; (2) populating it with the list of items/services for which prior authorization is required by the Medicare FFS program; and (3) populating it with the documentation rules for oxygen and Continuous Positive Airway Pressure (CPAP) devices. More information about the FFS Medicare program's efforts to support these Da Vinci use cases are available at *go.cms.gov/MedicareRequirementsLookup.*

We encourage all payers, including but not limited to MA organizations, Medicaid managed care plans and CHIP managed care entities, and QHP issuers in FFEs to follow CMS's example and align with the Da Vinci Project to: (1) Develop a similar lookup service; (2) populate it with their list of items/services for which prior authorization is required; and (3) populate it with the documentation rules for at least oxygen and CPAP. By taking this step, health plans can join CMS in helping to build an ecosystem that will allow providers to connect their EHRs or practice management systems and efficient work flows with up-to-date information on which items and services require prior authorization and what the documentation requirements are for various items and services under that patient's current plan enrollment.

In the 8 years since the first HHS rulemakings to implement HITECH, significant progress has been made in the adoption of EHRs by hospitals and clinicians; however, progress on interoperability needs to be accelerated.

In section 106(b) of MACRA, Congress declared it a national objective to achieve widespread exchange of health information through interoperable certified EHR technology nationwide by December 31, 2018. Not later than July 1, 2016, the Secretary was to establish metrics to be used to determine if and to the extent this objective was achieved. If the objective is not achieved by December 31, 2018, the Secretary must submit a report not later than December 31, 2019, that identifies barriers to the objective and recommends actions that the federal government can take to achieve the objective. In April 2016, ONC published the ''Office of the National Coordinator for Health Information Technology; Medicare Access and CHIP Reauthorization Act of 2015; Request for Information Regarding Assessing Interoperability for MACRA'' RFI (81 FR 20651). Based on stakeholder input received in response to the RFI, ONC subsequently identified the following two metrics for interoperability (see *https://www.healthit.gov/sites/default/files/fulfilling_section_106b1c_of_the_medicare_access_and_chip_reauthorization_act_of_2015_06.30.16.pdf*):

- Measure #1: Proportion of health care providers who are electronically engaging in the following core domains of interoperable exchange of health information: sending, receiving, finding (querying), and integrating information received from outside sources.
- Measure #2: Proportion of health care providers who report using the information they electronically receive from outside providers and sources for clinical decision-making.

ONC recently provided an update on these metrics in its 2018 Report to

Congress—Annual Update on the Adoption of a Nationwide System for the Electronic Use and Exchange of Health Information (see *https://www.healthit.gov/sites/default/files/page/2018-12/2018-HITECH-report-to-congress.pdf*). ONC will continue to evaluate nationwide performance according to the identified metrics, and believes current developments, such as policy changes being implemented under the 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) will contribute to increasingly improved performance under these metrics.

In addition, the Cures Act included provisions to advance interoperability and health information exchange, including, for example, enhancements to ONC's Health IT certification program and a definition of ''information blocking'' (as discussed further in section VIII. of this proposed rule). These provisions have been addressed in depth in ONC's proposed rule ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (published elsewhere in this issue of the **Federal Register**).

Section 4003 of the Cures Act added a definition of ''interoperability'' as paragraph 10 of section 3000 of the PHSA (42 U.S.C. 300jj (9)) (as amended). Under section 3000 of the PHSA, 'interoperability', with respect to health IT, means technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health IT without special effort on the part of the user. It also allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law and does not constitute information blocking as defined in section 3022(a) of the PHSA.

This definition aligns with the definition under MACRA and the HHS vision and strategy for achieving a health information ecosystem within which all individuals and their health care providers are able to send, receive, find, and use electronic health information in a manner that is appropriate, secure, timely, and reliable to support the health and wellness of individuals through informed shared decision-making, as well as through patient choice of health plans and providers. Accordingly, except where we further or otherwise specify for a specific policy or purpose, when we use the term ''interoperability'' within this proposed rule we are referring to the definition in section 3000 of the PHSA.

E. Challenges and Barriers to Interoperability

Through significant stakeholder feedback, we understand that there are many barriers to interoperability which have obstructed progress over the years. We have conducted stakeholder meetings and roundtables; solicited comments via RFIs; and received additional feedback through letters and rulemaking. All of this input together has contributed to our proposals in this proposed rule. Some of the main barriers shared with us are addressed in the following sections. While we have made efforts to address some of these barriers in this proposed rule and through prior rules and actions, we believe there is still considerable work to be done to overcome some of these considerable challenges toward achieving interoperability.

1. Patient Identifier and Interoperability

In the Interoperability RFI in the FY 2019 IPPS proposed rule (83 FR 20550), we solicited feedback on positive solutions to better achieve interoperability or the sharing of health care information between providers. A number of commenters noted that the lack of a unique patient identifier (UPI) inhibited interoperability efforts because, without a unique identifier for each patient, the safe and secure electronic exchange of health information is constrained because it is difficult to ensure that the relevant records are all for the same patient.

As part of efforts to reduce the administrative costs of providing and paying for health care, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191, enacted August 21, 1996) required the adoption of a ''unique individual identifier for healthcare purposes,'' commonly referred to as a UPI. At the time HIPAA was enacted, HHS began to consider what information would be needed to develop a rule to adopt a UPI standard. An initial Notice of Intent to issue a proposed rule on requirements for a unique health identifier for individuals was published in the November 2, 1998 **Federal Register** (63 FR 61773–61774).

Such an identifier has the potential to facilitate the accurate portability of health information by allowing correct patient matching because the universal identifier allows for accurate and timely patient record linking between providers across the care continuum and it allows a patient's complete record to easily move with them from provider to provider. However, stakeholders immediately raised significant concerns regarding the impact of this UPI on health information security and privacy. Stakeholders were concerned that if there was a single identifier used across systems, it would be easier for that information to be compromised, exposing protected health information (PHI) more easily than in the current medical record environment that generally requires linking several pieces of personally identifying information to link health records.

The National Committee on Vital Health Statistics (NCVHS), the statutory public advisory body to the Secretary of Health and Human Services (the Secretary) for health data, statistics, privacy, and national health information policy and HIPAA, conducted extensive hearings in the first year after HIPAA was enacted to evaluate this and other HIPAA-related implementation issues. The NCVHS First Annual Report to the Congress on the Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act, February 3, 1998, outlines the NCVHS' efforts to obtain feedback on the UPI (*https://ncvhs.hhs.gov/wp-content/uploads/2018/03/yr1-rpt-508.pdf*). Through this process, NCVHS found a lack of consensus on how best to define a UPI and controversy around the use of a UPI due to privacy and data security concerns. Those in favor of adopting a UPI believe a UPI is the most efficient way to foster information sharing and accurate patient record linking, where those against it are concerned about patient privacy and data security. NCVHS found these privacy and data security concerns outweighed the benefits of a UPI.

The NCVHS recommended that the Secretary not move forward with a proposed rule on a patient identifier until further discussions could be had to fully understand the privacy and data security concerns, as well as the full breadth of options beyond a single identifier. NCVHS suggested the Secretary work to maximize public participation in soliciting a variety of options for establishing an identifier or an alternative approach for identifying individuals and linking health information of individuals for health purposes.

Appreciating the significant concerns raised by stakeholders regarding implementing a UPI, Congress included language in the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, enacted October 21, 1998) and in each subsequent Appropriations bill, stating ''None of the funds made available in this Act may be used to

promulgate or adopt any final standard under section 1173(b) of the Act (42 U.S.C. 1320d–2(b)) providing for, or providing for the assignment of, a unique health identifier for an individual (except in an individual's capacity as an employer or a health care provider), until legislation is enacted specifically approving the standard.'' This language has effectively prohibited HHS from engaging in rulemaking to adopt a UPI standard. Consequently, the Secretary withdrew the Notice of Intent to pursue rulemaking on this issue on August 9, 2000 (*https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=200010&RIN=0938-AI91*).

In recent years, concerns regarding the privacy and security of information have only increased. For example, in the first quarter through third quarter of FY 2018 (October 1, 2017 through June 30, 2018), 276 breach incidents were reported to the HHS Office of Civil Rights (OCR) affecting 4,341,595 individuals (*https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf*).

Although the appropriations language regarding the UPI standard has remained unchanged, in the report accompanying the 2017 appropriations bill, Congress additionally stated, ''Although the Committee continues to carry a prohibition against HHS using funds to promulgate or adopt any final standard providing for the assignment of a unique health identifier for an individual until such activity is authorized, the Committee notes that this limitation does not prohibit HHS from examining the issues around patient matching. Accordingly, the Committee encouraged the Secretary, acting through ONC and CMS, to provide technical assistance to private-sector led initiatives to develop a coordinated national strategy that will promote patient safety by accurately identifying patients to their health information.'' (H.R. Rep. No. 114–699, p. 110, *https://www.gpo.gov/fdsys/pkg/CRPT-114hrpt699/pdf/CRPT-114hrpt699.pdf*). Congress has repeated this guidance for 2018 and 2019. This guidance directed HHS to focus on examining issues around patient matching and to provide technical assistance to private sector-led initiatives focusing on a patient matching solution.

Unlike a UPI, which assigns a unique identifier—either numerical or otherwise—to each patient, patient matching is a process by which health information from multiple sources is compared to identify common elements, with the goal of identifying records representing a single patient. This is generally done by using multiple demographic data fields such as name, birth date, gender, and address. The goal of patient matching is to link one patient's data across multiple databases within and across health care providers in order to obtain a comprehensive view of that patient's health care information.

ONC has stated that patient matching is critically important to interoperability and the nation's health IT infrastructure as health care providers must be able to share patient health information and accurately match a patient to his or her data from a different provider in order for many anticipated interoperability benefits to be realized.

Patient matching can be less precise than a UPI due to the reliance on demographic attributes (such as name and date of birth) which are not unique traits to a particular patient; further, patient matching is often dependent on manual data entry and data maintained in varying formats. Matching mistakes can contribute to adverse events, compromised safety and privacy, and increased health care costs (see *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*). However, a wide range of strategies and best practices currently being deployed across the industry have been shown to improve patient matching rates, suggesting that patient matching approaches can be an effective solution when appropriately implemented (see *https://www.healthit.gov/sites/default/files/patient_identification_matching_final_report.pdf*).

Many stakeholders commenting on the interoperability RFIs included in the 2019 proposed payment rules indicated that patient matching is a ''core functionality'' of patient identification and necessary to ensure care coordination and the best patient outcomes. Commenters also noted that a consistently used matching strategy could accomplish the original goals of a UPI with a diminished risk to individual privacy and health information security.

Several commenters noted that the lack of a UPI impacted interoperability, but finding a suitable and consistent matching strategy could address this issue. These commenters often specifically supported Congress' guidance to have ONC and CMS provide technical assistance to the private sector to identify this strategy. To help jump start the process of finding a solution to patient matching, ONC launched the Patient Matching Algorithm Challenge in 2017, awarding six winners $75,000 in grants in late 2017 (*https://www.patientmatchingchallenge.com/challenge-information/challenge-details*). The goal of the Patient Matching Algorithm Challenge was to bring about greater transparency and data on the performance of existing patient matching algorithms, spur the adoption of performance metrics for patient data matching algorithm vendors, and positively impact other aspects of patient matching such as deduplication and linking to clinical data.

We continue to support ONC's work promoting the development of patient matching initiatives. Per Congress' guidance, ONC is looking at innovative ways to provide technical assistance to private sector-led initiatives to further develop accurate patient matching solutions in order to promote interoperability without requiring a UPI.

We understand the significant health information privacy and security concerns raised around the development of a UPI standard and the current prohibition against using HHS funds to adopt a UPI standard. Recognizing Congress' statement regarding patient matching and stakeholder comments stating that a patient matching solution would accomplish the goals of a UPI, we seek comment for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. We also seek comment on how we may leverage our program authority to provide support to those working to improve patient matching. In addition, we intend to use comments for the development of policy and future rulemaking.

2. Lack of Standardization

Lack of standardization inhibits the successful exchange of health information without additional effort on the part of the end user. To achieve secure exchange of health information across health IT products and systems that can be readily used without special effort by the user, both the interface technology and the underlying data must be standardized, so all systems are ''speaking the same language.'' Consistent use of modern computing standards and applicable content standards (such as clinical vocabularies) are fundamental to achieving full-scale technical interoperability (systems can connect and exchange data unaltered) and semantic interoperability (systems can interpret and use the information that has been exchanged). Lack of such standards creates a barrier to

interoperability. Where specific standards are not consistently used, particularly to structure exchange interfaces such as APIs, the exchange is more difficult and expensive than it needs to be and the recipient of exchanged data must often undertake substantial special effort to make sense of the information.

In this proposed rule, similar to CMS' Blue Button 2.0 approach for Medicare FFS,[3] we propose to require that all MA organizations, Medicaid managed care plans, CHIP managed care entities, Medicaid state agencies, CHIP agencies that operate FFS systems, and issuers of QHPs in the FFEs, deploy standardized, open APIs to make certain information available to enrollees as discussed in section III. of this proposed rule.

The lack of a sufficiently mature API functionality technical standard has posed a challenge and impediment to advancing interoperability. In 2015, ONC finalized an API functionality certification criterion in the ''2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' Final Rule (2015 Edition final rule) (80 FR 62602). However, while a consensus technical standard specific to the API technical functionality was in development, it had not yet matured enough for inclusion in the 2015 Edition final rule, which does not identify a specific standard for API functionality.

As discussed in greater detail in section II of this proposed rule, we believe that a specific foundational standard for API functionality has matured sufficiently enough for ONC to propose it for HHS adoption (published elsewhere in this issue of the **Federal Register**). To take full advantage of this proposed standard, as well as already adopted standards applicable to content exchanged via APIs, we propose in sections II. and III. of this proposed rule to require that MA organizations, Medicaid managed care plans, Medicaid state agencies, CHIP managed care entities, CHIP agencies that operate FFS systems, and QHP issuers in FFEs comply with the ONC-proposed regulations for this standard. Those proposed regulations would require deployment of API technologies conformant with the API technical standard proposed by ONC for HHS adoption at 45 CFR 170.215 and other applicable standards such as content and vocabulary standards adopted at 45 CFR part 162 and 42 CFR 423.160, and proposed by ONC for HHS adoption at 45 CFR 170.213 (published elsewhere in this issue of the **Federal Register**). Furthermore, we note that we intend to continue to work with stakeholders to develop standards that will advance interoperability.

3. Information Blocking

As explained above, information blocking is defined in section 3022(a) of the PHSA. Understanding this definition, information blocking could be considered to include the practice of withholding data, or intentionally taking action to limit or restrict the compatibility or interoperability of health IT. Through stakeholder outreach, roundtables, and letters we have received, we understand that health care providers may limit or prevent data exchange in an effort to retain patients. By withholding a patient's health information from competing health care providers, a health care provider can effectively inhibit a patient from freely moving within the health care market because that patient would not otherwise have access to their complete health information.

We additionally understand from stakeholder feedback that in certain cases a health IT vendor has prohibited the movement of data from one health IT system to another in an effort to maintain their customer base.

Information blocking is a significant threat to interoperability and can limit the ability for providers to coordinate care and treat a patient based on the most comprehensive information available. In sections VIII.B. and C. of this proposed rule we propose to publicly report the names of clinicians and hospitals who submit a ''no'' response to certain attestation statements related to the prevention of information blocking in order to deter health care providers from engaging in conduct that could be considered information blocking.

Preventing and avoiding information blocking is important to advancing interoperability. We believe this proposal would help discourage health care providers from information blocking and clearly indicates CMS's commitment to preventing such practices.

4. Lack of Adoption/Use of Certified Health IT Among Post-Acute Care (PAC) Providers

PAC facilities are critical in the care of patients' post-hospital discharge, and can be a determining step in the health progress for those patients.[4] Interoperable health IT can improve the ability of these facilities to coordinate and provide care; however, long-term care and PAC providers, such as nursing homes, home health agencies (HHAs), long-term care providers, and others, were not eligible for the EHR Incentive Programs under the HITECH Act. Based on the information we have, we understand that this was a contributing factor to these providers not adopting CEHRT at the same rate as eligible hospitals and physicians, who were able to adopt CEHRT using the financial incentives provided under the programs.[5] [6]

While a majority of skilled nursing facilities (SNFs) used an EHR in 2016 (64 percent), there is considerable work to be done to increase adoption and the exchange of data in this provider population. In that same year, only three out of 10 SNFs electronically exchanged (that is, sent or received) key clinical health information, and only 7 percent had the ability to electronically send, receive, find, and integrate patient health information. In 2017, an ONC survey found that more HHA) (78 percent) adopted EHRs than SNFs (66 percent), but integration of received information continued to lag behind for both HHAs (36 percent) and SNFs (18 percent). While both ONC surveys focused on SNFs, it is important to note the large provider overlap between SNFs and other nursing facilities. In 2014, 14,409 out of 15,640 (92 percent) of nursing homes were certified for both Medicare and Medicaid.[7]

Long-term hospitals, inpatient rehabilitation facilities (IRFs), SNFs, and HHAs are required to submit to CMS standardized patient assessment data described in section 1899B(b)(1) of the Act (as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, enacted October 6, 2014)). We have defined the term ''standardized patient assessment data'' (or ''standardized resident assessment data'' for purposes of SNFs) as patient or resident assessment questions and

[3] We refer readers to *https://bluebutton.cms.gov* for more information related to the CMS Blue Button initiative.

[4] *https://www.healthit.gov/sites/default/files/electronic-health-record-adoption-and-interoperability-among-u.s.-skilled-nursing-facilities-in-2016.pdf.*

[5] *https://aspe.hhs.gov/report/opportunities-engaging-long-term-and-post-acute-care-providers-health-information-exchange-activities-exchanging-interoperable-patient-assessment-information/hit-and-ehr-certification-ltpac.*

[6] *https://www.healthit.gov/sites/default/files/pdf/HIT_LTPAC_IssueBrief031513.pdf.*

[7] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Certification andComplianc/Downloads/nursinghome datacompendium_508-2015.pdf.*

response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply. Section 1899B(b)(1)(B) of the Act states that the categories for which standardized patient or resident assessment data must be submitted include, at a minimum, functional status; cognitive function; medical conditions and co-morbidities; special services, treatments and interventions; and impairments. Section 1899B(b)(1)(A) of the Act requires that such data must be submitted through the applicable reporting provision that applies to each PAC provider type using the PAC assessment instrument that applies to the PAC provider. Section 1899B(a)(1)(B) of the Act additionally requires that these data be standardized and interoperable so as to allow for their exchange among health care providers, including PAC providers, to ensure coordinated care and improved Medicare beneficiary outcomes as these patients transition throughout the care continuum. To enable the interoperable exchange of such information, we have adopted certain patient assessment data elements as standardized patient or resident assessment data and mapped them to appropriate health IT standards which can support the exchange of this information. For more information, we refer the reader to the CMS website at *https://del.cms.gov/DELWeb/pubHome.*

5. Privacy Concerns and HIPAA

The Privacy, Security, and Breach Notification Rules under HIPAA (45 CFR parts 160 and 164) support interoperability by providing assurance to the public that PHI as defined in 45 CFR 160.103 is maintained securely and shared only for appropriate purposes or with express authorization of the individual. For more than a decade, the HIPAA Rules have provided a strong privacy and security foundation for the health care system. However, we have heard that lack of harmonization between federal and state privacy and security standards can create uncertainty or confusion for HIPAA covered entities that want to exchange health information. Resources about how the HIPAA Rule permits health care providers and health plans to share health information using health IT for purposes like treatment or care coordination is available on the HHS OCR website. See *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/permitted-uses/index.html.*

Although barriers to interoperability do exist, HHS and private industry are actively working to address them. On June 6, 2018, the HHS Deputy Secretary initiated the Regulatory Sprint to Coordinated Care (RS2CC). In support of this effort, the HHS Office of Inspector General (OIG) released an RFI on barriers to coordinated care or value-based care, which was out for public comment through October 26, 2018 (83 FR 43607). Together, CMS and ONC are working to address information blocking via rulemaking. We are actively working to improve data standardization, particularly through the use of APIs. And, we are using available policy levers to encourage greater adoption of EHR technology and interoperability among PAC providers. We provide resources to help providers see how HIPAA and interoperability work together. And, we are leveraging private sector relationships to find patient matching solutions in lieu of a patient identifier.

F. Summary of Major Provisions

To empower beneficiaries of Medicaid and CHIP FFS programs and enrollees in MA organizations, Medicaid and CHIP managed care entities, and QHP issuers in the FFEs (when mentioned throughout this proposed rule, this includes QHPs certified by FFEs regardless of whether enrollees enroll through the FFE or off the FFE), we are proposing several initiatives to break down the barriers that impede patients' ease of access to their electronic health care information; we propose to create and implement new mechanisms for them to access to their own health care information, as well as the ability to decide how, when, and with whom to share their information. We are proposing to require that a variety of information be made accessible to these impacted patients via ''openly published'' (or simply ''open'') APIs–that is, APIs for which the technical and other information required for a third-party application to connect to them is publicly available. This will provide these patients with convenient access to their health care information in accordance with the HIPAA Privacy Rule access standard at 45 CFR 164.524, and an increase in their choice of applications with which to access and use their own electronic health information, as discussed above, and other information relevant to managing their health, enabling open APIs to improve competition and choice as they have in other industries. We propose to require MA organizations, Medicaid state agencies, state CHIP agencies, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs (by requiring them to comply with the proposed ONC standard) to implement open APIs consistent with the API technical standards proposed by ONC for adoption by HHS and to use content and vocabulary standards adopted by HHS at 45 CFR part 162 and 42 CFR 423.160, and proposed by ONC for adoption by HHS at 45 CFR 170.213 (published elsewhere in this issue of the **Federal Register**).

Effective coordination and appropriate sharing of enrollee information between health plans can reduce the need for providers to write duplicative letters of medical necessity, or it could reduce instances of subjecting beneficiaries to unnecessary repetition of step therapy, or repeated utilization reviews, risk screenings and assessments. It could also help to streamline prior authorization procedures or reduce instances where the clinician might need to intervene personally with a payer to ensure his or her patient received the treatment necessary. We are proposing to require payers to support beneficiaries in coordinating their own care via payer to payer care coordination. In addition to existing care coordination efforts between plans, we propose that a plan must, if asked by the beneficiary, forward his or her information to a new plan or other entity designated by the beneficiary for up to 5 years after the beneficiary has disenrolled with the plan. Such transactions would be made in compliance with applicable laws. We are proposing a requirement for MA Plans, Medicaid and CHIP Managed Care entities (MCOs, PIHPs, PAHPs), and QHP issuers in FFEs to coordinate care between plans by exchanging, at a minimum, the data elements in the United States Core Data for Interoperability (USCDI) standard [8] at enrollee request at specified times.

We believe that payers' ability to share enrollee claims, encounter data, utilization history, and clinical health information they may have for their enrollees with one another, as well as their ability to share that information with patients and health care providers, when approved by the patient and appropriate under applicable law, using interoperable electronic means will considerably improve patient access to information, reduce provider burden, and reduce redundant and otherwise unnecessary data-related policies and procedures. We are proposing to require that all MA organizations, Medicaid and CHIP Managed Care entities (MCOs, PIHPs, and PAHPs), and QHP issuers in FFEs (with the exception of stand-alone dental plans (SADPs)) must participate in a trusted health information exchange network meeting criteria for

[8] For more information on the USCDI, see *https://www.healthit.gov/USCDI.*

interoperability. Further, we discuss an approach to payer-to-payer and payer-to-provider interoperability which leverages such existing trusts networks.

States and CMS routinely exchange data to support the administration of benefits to Medicare-Medicaid dually eligible beneficiaries. This includes ''buy-in'' data on who is enrolled in Medicare, and who is liable for paying the dual eligible beneficiary's Part A and B premiums. Buy-in data exchanges support state, CMS, and Social Security Administration (SSA) premium accounting, collections, and enrollment functions. This also includes ''MMA'' data on dual eligibility status (called the ''MMA file'' after the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted December 8, 2003)), which are used in all four Parts of Medicare. We are proposing to establish frequency requirements to require all states to participate in daily exchange of buy-in data with CMS by April 1, 2022, and to update frequency requirements to require all states to submit MMA file data to CMS daily by April 1, 2022.

We are actively working with our partners throughout HHS to deter the practice of information blocking. We believe it would benefit patients to know if their health care providers attested negatively to any of the prevention of information blocking attestation statements under the Quality Payment Program (QPP) or the Medicare FFS Promoting Interoperability Program. In previous testing with patients and caregivers, we have learned that effective use of CEHRT is important to them when making informed health care decisions. To address this issue, we are proposing to publicly post information about negative attestations on appropriate CMS websites.

Section 4003 of the Cures Act recognized the importance of making provider digital contact information available through a common directory. To facilitate this, CMS has updated the National Plan and Provider Enumeration System (NPPES) to be able to capture this digital contact information. Now that the systems are in place, we seek to increase the number of clinicians with valid and current digital contact information available through NPPES. We are proposing to publicly identify those clinicians who have not submitted digital contact information in NPPES. Further, we are proposing to align program requirements for MA organizations, Medicaid state agencies, Medicaid managed care plans, CHIP agencies that operate FFS systems, CHIP managed care entities, and QHP issuers in FFEs (with the exception of issuers of SADPs) such that each payer/plan issuer would make provider directory information publicly available via an API.

Electronic patient event notifications from hospitals, or clinical event notifications, are widely recognized as an effective tool for improving care coordination across settings, especially for patients at admission, discharge, and transfer. We are proposing to revise the conditions of participation for hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals) and CAHs to require that these entities send patient event notifications to another health care facility or to another community provider. We propose to limit this requirement to only those Medicare- and Medicaid-participating hospitals and CAHs that possess EHRs systems with the technical capacity to generate information for electronic patient event notifications.

We also plan to test ways to promote interoperability across the health care spectrum through models tested by the Center for Medicare and Medicaid Innovation (''Innovation Center''). Innovation Center models offer a unique opportunity to engage with health care providers and other entities in innovative ways and to test concepts that have the ability to accelerate change in the U.S. health care system, including to promote interoperability. As such, we are soliciting public comment on general principles around interoperability within Innovation Center models for integration into new models, through provisions in model participation agreements or other governing documents. In applying these general principles, we intend to be sensitive to the details of individual model design, and the characteristics and capacities of the participants in each specific model.

One of the many proposals we considered but did not include in this proposed rule was a proposal to make updates to the Promoting Interoperability Program (formerly the Medicare and Medicaid EHR Incentive Programs) to encourage eligible hospitals and CAHs to engage in certain activities focused on interoperability. This concept was initially introduced in a request for public comment in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20537 through 20538). We discussed a possible future strategy in which we would create a set of priority health IT or ''interoperability'' activities that would serve as alternatives to measures in the Promoting Interoperability Program. We discussed creating a set of priority health IT activities with a focus on interoperability and simplification to reduce health care provider burden while allowing flexibility to pursue innovative applications of health IT to improve care delivery. We offered three different examples of activities which might be included under such an approach, including:

- Participation in, or serving as, a health information network which is part of the Trusted Exchange Framework and Common Agreement (TEFCA);
- Maintaining an open API which allows persistent access to third parties which enables patients to access their health information; and
- Participating in piloting and testing of new standards that support emerging interoperability use cases.

While we are not proposing this here, we expect to introduce a proposal for establishing ''interoperability activities'' in the FY 2020 IPPS/LTCH PPS rulemaking in conjunction with other updates to the Promoting Interoperability Program. To help inform future rulemaking, we invite comments on the concepts discussed above, as well as other ideas for ''interoperability activities'' for which eligible hospitals and CAHs could receive credit in lieu of reporting on program measures.

Finally, we include two RFIs. One related to interoperability and health IT adoption in PAC settings, and one related to the role of patient matching in interoperability and improved patient care.

II. Technical Standards Related to Interoperability

A. Technical Approach and Standards

1. Use of FHIR for APIs

The MACRA defines interoperability as the ability of two or more health information systems or components to exchange clinical and other information and to use the information that has been exchanged using common standards such as to provide access to longitudinal information for health care providers in order to facilitate coordinated care and improved patient outcomes. Interoperability is also defined in section 3000 of the Public Health Service Act (PHSA) (42 U.S.C. 300jj), as amended by section 4003 of the Cures Act. Under that definition, ''interoperability'', with respect to health IT, means such health IT that enables the secure exchange of electronic health information with, and use of electronic health information from, other health IT without special

effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and does not constitute information blocking as defined in section 3022(a) of the PHSA, which was added by section 4004 of the Cures Act. We believe the PHSA definition is consistent with the MACRA definition of interoperability. As noted at the outset of this proposed rule, for the purposes of this proposed rule and this specific section, we will use the PHSA definition.

We believe the PHSA definition of interoperability is useful as a foundational reference for our approach to advancing interoperability and exchange of electronic health information for individuals throughout the United States, and across the entire spectrum of provider types and care settings with which health plan issuers and administrators need to efficiently exchange multiple types of relevant data. We note the PHSA definition of interoperability is not applied only to a specific program or initiative but to all activities under the title of the PHSA that establishes ONC's responsibilities to support and shape the health information ecosystem, including exchange infrastructure for the United States health care system as a whole. The PHSA definition of interoperability is also consistent with HHS's vision and strategies for achieving a health information ecosystem within which all individuals, their families, and health care providers are able to send, receive, find, and use electronic health information in a manner that is appropriate, secure, timely, and reliable to support the health and wellness of individuals through informed, shared decision-making,[9] as well as to support consumer choice of health plans and providers.

A core policy principle we aim to support across all proposals in this proposed rule is that every American should be able, without special effort or advanced technical skills, to see, obtain, and use all electronically available information that is relevant to their health, care, and choices—of plans, providers, and specific treatment options. This includes two types of information: Information specifically about the individual that requires appropriate diligence to protect the individual's privacy, such as their current and past medical conditions and care received, as well as information that is of general interest and should be widely available, such as plan provider networks, the plan's formulary, and coverage policies.

While many consumers today can often access their own electronic health information through patient/enrollee portals and proprietary applications made available by various providers and health plans, they must typically go through separate processes to obtain access to each system, and often need to manually aggregate information that is delivered in various, often non-standardized, formats. The complex tasks of accessing and piecing together this information can be burdensome and frustrating to consumers.

In contrast, consider the ease with which consumers can choose and use a navigation application which integrates information on their current location, preferences, and real-time traffic conditions to choose the best route to a chosen destination. Consumers do not have to log into a different ''location'' portal to learn their current geographic coordinates, write them down, and then log into a separate ''map'' portal to enter their current coordinates to request directions to their destination.

An API can be thought of as a set of commands, functions, protocols, or tools published by one software developer (''A'') that enable other software developers to create programs (applications or ''apps'') that can interact with A's software without needing to know the internal workings of A's software, all while maintaining consumer privacy data standards. This is how API technology enables the seamless user experiences associated with applications familiar from other aspects of many consumers' daily lives, such as travel and personal finance. Standardized, transparent, and pro-competitive API technology can enable similar benefits to consumers of health care services.[10]

While acknowledging the limits of our authority to require use of APIs to address our goals for interoperability and data access, we are proposing in this rule to use our programmatic authority in Medicare, Medicaid, CHIP, and over QHPs in FFEs to advance these goals. Therefore, we are proposing to require that a variety of data be made accessible to MA enrollees, Medicaid beneficiaries, CHIP enrollees, and enrollees in QHPs in FFEs, by requiring that MA organizations, Medicaid state agencies, Medicaid managed care plans, CHIP agencies, CHIP managed care entities, and QHPs in FFEs, adopt and implement ''openly published'' (or simply ''open'') APIs. Having certain data available through open APIs would allow these enrollees to use the application of their choice to access and use their own electronic health information and other information relevant to managing their health.

Much like our efforts under the Medicare Blue Button 2.0 and MyHealthEData initiatives, which made Parts A, B, and D claims data available to Medicare beneficiaries, our proposal would result in claims and coverage information being accessible for the vast majority of Medicare beneficiaries by requiring MA organizations to take new steps—by implementing the API described in this proposed rule—to make claims data available to their enrollees. We expect that our proposal would also benefit all Medicaid beneficiaries because our proposal applies to Medicaid state agencies (which administer Medicaid FFS programs), and all types of Medicaid managed care plans (MCOs, PIHPs, and PAHPs), and CHIP agencies (which administer CHIP FFS) and CHIP managed care entities (MCOs, PIHPs, and PAHPs). Finally, while our proposal is only applicable to QHPs in FFEs, we hope that states operating Exchanges might consider adopting similar requirements for QHPs in State-Based Exchanges (SBEs), and that other payers in the private sector might consider voluntarily offering data accessibility of the type included in this proposal so that even more patients across the American health care system can easily have and use such information to advance their choice and participation in their health care. We hope that the example being set by CMS will raise consumers' expectations and encourage other payers in the market to take similar steps to advance patient access and empowerment outside the scope of our proposed requirements.

An ''open API,'' for purposes of this proposed rule, is simply one for which the technical and other information required for a third-party application to connect to it is openly published. Open API does not imply any and all applications or application developers would have unfettered access to people's personal or sensitive information. Rather, an open API's published technical and other information specifically includes what an application developer would need to

[9] See, for example, ONC ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'' Final Version 1.0 (2015): *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1Nor.0.pdf.*

[10] ONC has made available a succinct, non-technical overview of APIs in context of consumers' access to their own medical information across multiple providers' EHR systems, which is available at the HealthIT.gov website at *https://www.healthit.gov/api-education-module/story_html5.html.*

know to connect to and obtain data available through the API.

We recommend reviewing the discussion of the standardized API criterion and associated policy principles and technical standards included in ONC's proposed rule ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (published elsewhere in this issue of the **Federal Register**) for those seeking more detailed information on API functionality and interoperability standards relevant to electronic health information. While that discussion is specific to health IT certified under ONC's Health IT Certification Program rather than the information systems generally used by payers and plan issuers for claims, encounters, or other administrative or plan operational data, it includes information applicable to interoperability standards, as well as considerations relevant to establishing reasonable and non-discriminatory terms of service for applications seeking to connect to the open API. However, it is important to reiterate that we are *not* proposing to require health plan issuers to use Health IT Modules certified under ONC's program to make administrative data such as claims history or provider directory information available to enrollees.

In developing this proposed rule, we considered how to advance the sort of interoperability and innovation in the health system supported by open APIs in other industries. We have also collaborated with ONC to align with and leverage relevant API policies ONC has proposed to implement Cures Act requirements. In general, we believe three attributes of open APIs are particularly important to achieve the goal of offering individuals convenient access, through applications they choose, to available and relevant electronic health information. The three API attributes are:

- The API technologies themselves, not just the data accessible through them, are standardized;
- The APIs are technically transparent; and
- The APIs are implemented in a pro-competitive manner.

In this section, we discuss these concepts generally and how they are applicable in the health care context for all payers, as well as explain how these are relevant to our specific proposals, which are discussed in detail in section III. of this proposed rule.

a. Standardized

Technical consistency and implementation predictability are fundamental to scale API-enabled interoperability and reduce the level and costs of custom development otherwise necessary to access, exchange, and use health information. From an industry standpoint, a consistent and predictable set of API functions, as well as content and formatting standards, provide the health IT ecosystem with known technical requirements against which application developers can build applications (including but not limited to ''mobile apps'') and other innovative services which users can select to access and manage the data they need. Therefore, to achieve interoperability consistent with the PHSA definition, the proposals in section III. of this proposed rule would effectively require that API technologies deployed by health plans subject to this rule use modern computing standards (such as RESTful interfaces [11] and XML/JSON), and present the requested information using widely recognized content standards (such as standardized vocabularies of clinical terms), where applicable.

b. Transparent

Transparency and openness around API documentation is commonplace in many other industries and has fueled innovation, growth, and competition. Documentation associated with APIs deployed by health care providers, health plans, and other entities engaged in exchanging electronic health information typically addresses the information that would be material to persons and entities that use or create software applications that interact with the API (API users). Information material to API users includes, but is not necessarily limited to, all terms and conditions for use of the API, including terms of service, restrictions, limitations, obligations, registration process requirements, or other similar requirements that would be needed to:

- Develop software applications to interact with the API;
- Connect software applications to the API to access electronic health information through the API;
- Use any electronic health information obtained by means of the API technology; and
- Register software applications to connect with the API.

As discussed in section III. of this proposed rule, we are proposing that certain entities (MA organizations, State Medicaid agencies, Medicaid managed care plan, State CHIP agencies, CHIP managed care entities, and QHPs in FFEs), supported by the suppliers of their API technology, and for the API technology they use to comply with the requirements we propose in this proposed rule, be required to make freely and publicly accessible the specific business and technical documentation necessary to interact with these APIs. Thus, we propose to require that these entities comply with the requirements that ONC has proposed that the Secretary adopt for developers and users of health IT certified to the API criteria at 45 CFR 170.315 (published elsewhere in this issue of the **Federal Register**).

c. Pro-Competitive

Pro-competitive practices in selecting, configuring, and maintaining APIs are those business practices that promote the efficient access to, exchange of, and use of electronic health information to support a competitive marketplace that enhances consumer value and choice of direct-to-consumer technology, health coverage, and care. We believe that an ultimate goal of all participants in the health care ecosystem is that individuals should be able to use an application they choose to connect and access, without special effort, their electronic health information held by health care providers, health plans, or any health information networks, within practical and prudent limits that do not needlessly hinder their ability to connect to the API in a persistent manner.

Such acceptable limits include technical compatibility and ensuring the application does not pose an unacceptable level of risk to a system when connecting to an API offered by that system, consistent with the HIPAA Privacy and Security Rules and guidance issued by the HHS OCR,[12] to which the Secretary delegated the authority to enforce HIPAA privacy and security requirements. Organizational policies and procedures needed to comply with any additional requirements under state laws that would apply in a given situation would also be viewed as necessary and not anti-competitive. Examples of practices

[11] ''RESTful interfaces'' are those that are consistent with Representational State Transfer (REST) architectural style and communications approaches to web services development.

[12] OCR enforces federal civil rights laws, conscience and religious freedom laws, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules, and provisions of the Patient Safety and Quality Improvement Act of 2005 (PSQIA) and the Patient Safety Rule (codified at 42 CFR part 3 (73 FR 70732)) protecting the confidentiality and privilege of patient safety work product as defined in PSQIA and 42 CFR part 3. Thus, within HHS, OCR has lead responsibility for interpreting, administering, and enforcing HIPAA regulations and developing guidance.

we would view as pro-competitive might include proactively advising enrollees they are not required to use only the organization's own or preferred applications to access, use, and share their health information. Such advice would be publicly available and include information relevant to the enrollee about how they could request access to their information through a third-party application of their choosing.

We recognize that organizations subject to the open API requirements proposed in section III. of this proposed rule need to take reasonable and necessary steps to fulfill the organizations' duties under all applicable laws and regulations to protect the privacy and security of personally identifiable information (PII), including but not limited to PHI under HIPAA as defined at 45 CFR 160.103; those privacy and security protection obligations remain applicable even in the context of complying with our proposal. However, we do not believe it is appropriate to use security and privacy concerns as an opportunity to engage in anti-competitive practices. Anti-competitive practices might include declining to assess the technical compatibility or security risk of an application provided to prospective enrollees by a competing plan, despite an enrollee request to disclose their PHI to that application through the API.

2. Privacy and Security Concerns in the Context of APIs

We have received a wide range of stakeholder feedback on privacy and security issues in response to prior proposals [13] about policies related to APIs that would allow consumers to use any app of their choosing to access PHI held by a HIPAA covered entity. This feedback includes concerns about potential security risks to PHI created by an API connecting to third-party applications.

We appreciate these concerns. Deploying API technology that offers consumers the opportunity to access their electronic health information that is held by a covered entity (which includes but is not limited to MA organizations, the Medicare Part A and B programs, the Medicaid program, CHIP, QHP issuers on the FFE, and other health plan issuers) does not lessen the covered entity's duties under HIPAA and other law to protect the privacy and security of information it holds, including but not limited to PHI. A covered entity implementing an API to enable individuals to access their health information must take reasonable steps to ensure an individual's information is only disclosed as permitted or required by applicable law. The entity must take greater care in configuring and maintaining the security functionalities of the API and the covered entities' electronic information systems to which it connects than would be needed if it was implementing an API simply to allow easier access to widely available public information.

HIPAA covered entities and their business associates continue to be responsible for compliance with the HIPAA Rules, the Federal Trade Commission Act (FTC Act), and all other laws applicable to their business activities including but not limited to their handling of enrollees' PHI and other data. As we state repeatedly throughout this proposed rule, nothing in this proposed rule is intended to alter or should be construed as altering existing responsibilities to protect PHI under the HIPAA Rules and requirements.

However, we note that a number of stakeholders may believe that they are responsible for determining whether an application to which an individual directs their PHI be disclosed applies appropriate safeguards for the information it receives. Based on the OCR guidance discussed below, covered entities are not responsible under the HIPAA Rules for the security of PHI once it has been received by a third-party application chosen by an individual.

Under the HIPAA Privacy Rule,[14] individuals have the right of access to inspect and receive a copy of a defined set of their PHI as detailed at 45 CFR 164.501. Specifically, as OCR has indicated in regulations and guidance, an individual can exercise their right of access to direct a covered entity to send their information to a third party. When responding to an access request, ''the same requirements for providing the PHI to the individual, such as the timeliness requirements, fee limitations, prohibition on imposing unreasonable measures, and form and format requirements, apply when an individual directs that the PHI be sent to another person or entity.'' [15] Moreover, a covered entity may not impose unreasonable measures on an individual requesting access that serve as barriers to or unreasonably delay the individual from obtaining access to their PHI.[16]

We refer readers to further OCR guidance on related issues, including: The liability of a covered entity in responding to an individual's access request to send the individual's PHI to a third party (FAQ 2039); [17] individuals' rights under HIPAA to have copies of their PHI transferred or transmitted to them in the manner they request, even if the requested mode of transfer or transmission is unsecure (FAQ 2060); [18] and, a covered entity's obligation under the HIPAA Breach Notification Rule if it transmits an individual's PHI to a third party designated by the individual in an access request, and the entity discovers the information was breached in transit (FAQ 2040).[19] Under the HIPAA Privacy Rule, as explained in OCR's interpretive guidance, ''individuals have the right under HIPAA to have copies of their PHI transferred or transmitted to them in the manner they request . . . as long as the PHI is 'readily producible' in the manner requested, based on the capabilities of the covered entity and transmission or transfer in such a manner would not present an unacceptable level of security risk to the PHI on the covered entity's systems, such as risks that may be presented by connecting an outside system, application, or device directly to a covered entity's systems (as opposed to security risks to PHI once it has left the systems)'' (HIPAA FAQ 2060).[20]

We have also noted stakeholder concerns about protections which apply to non-covered entities such as direct-

[13] For instance, see discussion of stakeholder comments in the 2015 Edition final rule at 80 FR 62676.

[14] More information on the Privacy Rule, including related rulemaking actions and additional interpretive guidance, is available at *https://www.hhs.gov/hipaa/for-professionals/privacy/index.html.*

[15] See § 164.524(c)(2) and (3), and 164.308(a)(1), OCR HIPAA Guidance/FAQ–2036: *https://www.hhs.gov/hipaa/for-professionals/faq/2036/can-an-individual-through-the-hipaa-right/index.html,* and OCR HIPAA Guidance/FAQ–2037: *https://www.hhs.gov/hipaa/for-professionals/faq/2037/are-there-any-limits-or-exceptions-to-the-individuals-right/index.html.*

[16] See, generally, the ''unreasonable measures'' heading of OCR HIPAA for professionals information web page at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html. See also* FAQ 2039—*https://www.hhs.gov/hipaa/for-professionals/faq/2039/what-is-the-liability-of-a-covered-entity-in-responding/index.html;* FAQ 2060: *https://www.hhs.gov/hipaa/for-professionals/faq/2060/do-individuals-have-the-right-under-hipaa-to-have/index.html;* FAQ 2040: *https://www.hhs.gov/hipaa/for-professionals/faq/2040/what-is-a-covered-entitys-obligation-under/index.html.*

[17] *https://www.hhs.gov/hipaa/for-professionals/faq/2039/what-is-the-liability-of-a-covered-entity-in-responding/index.html.*

[18] *https://www.hhs.gov/hipaa/for-professionals/faq/2060/do-individuals-have-the-right-under-hipaa-to-have/index.html.*

[19] *https://www.hhs.gov/hipaa/for-professionals/faq/2040/what-is-a-covered-entitys-obligation-under/index.html.*

[20] *https://www.hhs.gov/hipaa/for-professionals/faq/2060/do-individuals-have-the-right-under-hipaa-to-have/index.html.*

to-consumer applications. Stakeholders, as well as covered entities who may be required to send PHI to these applications, have noted concerns that unscrupulous actors could deploy direct-to-consumer applications specifically in order to profit from obtaining, using, or disclosing individuals' PHI (and potentially other information) in ways the individual either did not authorize or to which the individual would not knowingly consent.

When a non-HIPAA-covered entity discloses an individual's confidential information in a manner or for a purpose not consistent with the privacy notice and terms of use to which the individual agreed, the FTC has authority under the FTC Act to investigate and take action against unfair or deceptive trade practices. The FTC has applied this authority to a wide variety of entities. The FTC also enforces the FTC Health Breach Notification Rule, which applies to certain types of entities that fall outside of the scope of HIPAA, and therefore, are not subject to the HIPAA Breach Notification Rule.[21]

We recognize that this is a complex landscape for patients, who we anticipate will want to exercise due diligence on their own behalf in reviewing the terms of service and other information about the applications they consider selecting. Therefore, we propose in section III. of this proposed rule specific requirements on the payers subject to these proposed regulations to ensure enrollees have the opportunity to become more informed about how to protect their PHI, important things to consider in selecting an application, and where they can lodge a complaint if they believe a HIPAA covered entity or business associate may have breached their duties under HIPAA or if they believe they have been subjected to unfair or deceptive actions or practices related to a direct-to-consumer application's privacy practices or terms of use.

In some circumstances, information that would be required to be made available through an API per an enrollee's information request under this proposed rule—which we view as consistent with the enrollee's right of access from a covered entity under the Privacy Rule—may not be readily transferable through the API. For instance, the covered entity may not hold certain information electronically. However, such a scenario would in no way limit or alter responsibilities and requirements under other law (including though not limited to HIPAA Privacy, Security, and Breach Notification Rules) that apply to the organizations that would be subject to our proposed regulations. Even if the open API access requirements proposed in section III.C. of this proposed rule were to be finalized and implemented, the organization may still be called upon to respond to individuals' request for information not available through the API, or for all of their information through means other than the API. We encourage HIPAA covered entities or business associates to review the OCR website for resources on the individual access standard at *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html* to ensure they understand their responsibilities.

3. Specific Technical Approach and Standards

Achieving interoperability throughout the health system is essential to achieving an effective, value-conscious health system within which consumers are able to choose from an array of health plans and providers. An interoperable system should ensure that consumers can both easily access their electronic health information held by plans and routinely expect that their claims, encounter, and other relevant health history information will follow them smoothly from plan to plan and provider to provider without burdensome requirements for them or their providers to reassemble or re-document the information. Ready availability of health information can be especially helpful when an individual cannot access their usual source of care, for instance if care is needed outside their regular provider's business hours, while traveling, or in the wake of a natural disaster.

The specific proposals within this rule as described in section III.C.2. would impose new requirements on MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs (excluding issuers of SADPs) to implement standardized, transparent APIs. Using the API, these entities would be required to provide current and former enrollees with certain claims and encounter data and certain specific clinical information. These entities would also be required to make available through the API information already required to be widely available, such as provider directory and plan coverage information. In developing our proposal delineating the information that must be available through an API consistent with the proposed technical requirements, we were guided by an intent to have available through the API all of the individual's electronic health information held by the plan in electronic format that is compatible with the API or that can, through automated means, be accurately rendered compatible with representation through the API. We were also guided by an intent to make available through standardized, transparent API technology all of the provider directory and plan coverage information that is held in formats readily compatible with the API.

Both the API technology itself and the data it makes available must be standardized to support true interoperability. Therefore, we propose in section III.C.2.b. of this proposed rule to require compliance with both (1) ONC's 21st Century Cures Act proposed regulations regarding content and vocabulary standards for representing electronic health information and (2) technical standards for an API by which the electronic health information must be made available. For the proposals described in section III.C.2.b. of this proposed rule (which include purposes *other than* a HIPAA transaction, which is required to comply with standards adopted at 45 CFR part 162), we are proposing these requirements to comply with interoperability standards proposed for HHS adoption in ONC's 21st Century Cures Act proposed rule (published elsewhere in this issue of the **Federal Register**).

In proposing to require that regulated entities comply with ONC-proposed regulations (published elsewhere in this issue of the **Federal Register**), and therefore, use specified standards, we intend to preclude regulated entities from implementing API technology using alternative technical standards to those ONC proposes for HHS adoption at 45 CFR 170.215, including but not limited to those not widely used to exchange electronic health information in the U.S. health system. We further intend to preclude entities from using earlier versions of the technical standards adopted at 45 CFR 170.215 by requiring compliance with only specified provisions of 45 CFR part 170 and deliberately excluding others. Likewise, by proposing to require use of the content and vocabulary standards by requiring compliance with 42 CFR 423.160 and 45 CFR part 162, and proposed at 45 CFR 170.213, we intend to prohibit use of alternative technical standards that could potentially be used for these same data classes and elements, as well as earlier versions of the adopted standards named in 42 CFR

[21] *https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf.*

423.160, 45 CFR part 162 and proposed at 45 CFR 170.213.

While we intend to preclude regulated entities from using content and vocabulary standards other than those described in 42 CFR 423.160, 45 CFR part 162, or proposed 45 CFR 170.213 and 170.215, we recognize there may be circumstances which render the use of other content and vocabulary alternatives necessary. As discussed below, we propose to allow the use of other alternatives in two circumstances. First, where other content or vocabulary standards are expressly mandated by applicable law, we would allow for use of those other mandated standards. Second, where no appropriate content or vocabulary standard exists within 45 CFR part 162, 42 CFR 423.160, or proposed 45 CFR 170.213 and 170.215, we would allow for use of any suitable gap-filling options, as may be applicable to the specific situation.

We are using two separate rulemakings because ONC's 21st Century Cures Act proposed rule, which includes API interoperability standards proposed for HHS adoption, would have broader reach than the scope of this proposed rule. At the same time, we wish to assure stakeholders that the API standards required of MA organizations, state Medicaid agencies, state CHIP agencies, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs under this proposal would be consistent with the API standards proposed by ONC for HHS adoption because we would require that the regulated entities follow specified, applicable provisions of the ONC-proposed requirements.

Requiring that regulated entities comply with the regulations regarding standards in ONC's 21st Century Cures Act proposed rule will support greater interoperability across the health care system, as health IT products and applications that will be developed for different settings and use cases would be developed according to a consistent base of standards that supports more seamless exchange of information. We welcome public comment on the proposed required compliance with regulations regarding standards in this proposed rule to those proposed for adoption by HHS through ONC' 21st Century Cures Act proposed rule, as well as on the best method to provide support in identifying and implementing the applicable content and vocabulary standards for a given data element.

Finally, while we believe that the proposed required compliance with regulations regarding standards requirements in this proposed rule to those proposed by ONC for HHS adoption is the best approach, we seek public comment on an alternative by which CMS would separately adopt the proposed ONC standards identified throughout this proposed rule, as well as future interoperability, content and vocabulary standards. We anticipate that any such alternative would include incorporating by reference the FHIR and OAuth technical standards and the USCDI content and vocabulary standard (described in sections II.A.3.b. and II.A.3.a. of this proposed rule, respectively) in CMS regulation, and replacing references to ONC regulations at 45 CFR 170.215, 170.213, and 170.205, respectively. However, we specifically seek comment on whether this alternative would present an unacceptable risk of creating multiple regulations requiring standards or versions of standards across HHS' programs, and an assessment of the benefits or burdens of separately adopting new standards and incorporating updated versions of standards in CFR text on a program by program basis. Furthermore, we seek comment on: How such an option might impact health IT development timelines; how potentially creating multiple regulations regarding standards over time across HHS might impact system implementation; and other factors related to the technical aspect of implementing these requirements.

B. Content and Vocabulary Standards

The HHS-adopted content and vocabulary standards applicable to the data provided through the API will vary by use case and within a use case. For instance, content and vocabulary standards supporting consumer access vary according to what specific data elements MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP's in FFEs have available electronically. Where another law does not require use of a specific standard, we are proposing to require use of, in effect, a catalogue of content and vocabulary standards from which the regulated entities may choose in order to satisfy the proposed requirements in 42 CFR 422.119, 431.60, 457.730, 438.252, and 457.1233, and 45 CFR 156.221.

We propose in section III.C.2.b. of this proposed rule that the applicable entity must comply with regulations regarding certain content and vocabulary standards for data available through the API, where applicable to the data type or data element, unless an alternate standard is required by other applicable law. Specifically, we propose the applicable entity must use:

- Content and vocabulary standard ONC proposes for HHS adoption at 45 CFR 170.213 (USCDI Version 1) where such standards are the only available standards for the data type or element;
- HIPAA Administrative Simplification transaction standards under 45 CFR part 162 or the Part D e-prescribing transaction standards at 42 CFR 423.160 where required by other applicable law, or where such standards are the only available standards for the data type or element; or
- Where a specific data type or element might be encoded or formatted using either a 45 CFR part 162 or 42 CFR 423.160 standard or the USCDI Version 1 standard at 45 CFR 170.213, the applicable entity may use any of these content and vocabulary standards as determined appropriate for the data type or element. We describe these proposals in more detail below.

First, we propose in section III.C.2.b. of this proposed rule to require compliance with the ONC-proposed regulations regarding the content and vocabulary standard at 45 CFR 170.213 as applicable to the data type or data element. This is the USCDI Version 1 set of data classes that can be supported by commonly used standards, and establishes a minimum set of data classes that would be required to be interoperable nationwide.[22] The USCDI is designed to be expanded in an iterative and predictable way over time. On behalf of HHS, ONC has proposed to adopt the USCDI as a standard in its 21st Century Cures Act proposed rule (published elsewhere in this issue of the **Federal Register**). The USCDI Version 1 data sets proposed by ONC for HHS adoption at 45 CFR 170.213 also includes the standards that are referenced by certification criteria that are also adopted in 45 CFR part 170, to which health IT, such as Health IT Modules presented for certification under ONC's Health IT Certification Program, must conform. Developers of applications are already familiar with and commonly using these standards in products that interact with ONC-certified health IT. The payer and purchaser communities are also aware of and commonly using the 45 CFR part 170 standards, and many members of these communities actively participate in health-data-focused standards development organizations responsible for the creation of these standards. As a result, we believe that compliance with regulations requiring these standards for

[22] For more information on the USCDI, see *https://www.healthit.gov/USCDI.*

CMS' programs should not add new burdens to the industry. All standards adopted within 45 CFR part 170, including the USCDI standard ONC proposes for HHS adoption at 45 CFR 170.213, are, or are proposed by ONC to be incorporated by reference by HHS, at 45 CFR 170.299 (published elsewhere in this issue of the **Federal Register**).

Second, we propose to require that entities use standards specified at 45 CFR part 162 for HIPAA transactions as required by applicable law, as well as the standards specified at 42 CFR 423.160 for Part D e-prescribing transactions, as required by applicable law. We reiterate that this proposed rule would not alter these other regulations, and should not be construed as altering any organization's compliance requirements for these other regulations. The standards proposed in this regulation are intended for instances where other statutes and regulations do not dictate the standard by which regulated parties are to convey or otherwise make available electronic information.

Where there is no legally mandated standard applicable to a specific data type or data element in a particular exchange context, and the HIPAA Administrative Simplification transaction standards under 45 CFR part 162 or the Part D e-prescribing transaction standards at 42 CFR 423.160 are the only standards available for a specific data element or type, we propose to require entities subject to these proposals to use these HIPAA standards when making data available through the API. We further clarify that, for purposes of formatting, making available, and sending electronic data under this proposed rule, we would require compliance with: (1) The content and vocabulary standards identified in 45 CFR part 162 regardless of whether the entities are covered entities, and (2) the Part D e-prescribing standards in 42 CFR 423.160 to exchange e-prescribing and related data (such as drug formulary and preferred drug list data) regardless of whether they are conducting a Part D e-prescribing transaction.

Third, in information exchanges where applicable law does not mandate a certain standard and where a specific data type or element might be encoded or formatted using the 45 CFR part 162 or 42 CFR 423.160 standard, or the USCDI Version 1 standard at 45 CFR 170.213, we propose in section III.C.2.b. of this proposed rule that the regulated entities subject to our proposal would have the freedom to provide data through the API that complies with any of these format or encoding standards. Specifically, we believe payers should use standards that are most efficient and effective based on their existing systems, data mapping considerations, or those standards that best meets enrollees' needs, while remaining technically practicable for use in conjunction with API technology conformant to the 45 CFR 170.215 proposed standards (published elsewhere in this issue of the **Federal Register**), and so long as such action is in accordance with applicable laws. For example, for data types for which 45 CFR part 162 standards are the only ones widely used throughout the payer community, and for specific content that payers typically only receive according to these HIPAA standards, we believe use of the 45 CFR part 162 content standards to represent the information is appropriate and efficient at this juncture. We note that for data made available through the API, entities subject to this proposal would be required to use the standards identified in this proposal even if the exact information to be exchanged through the API is also required to be available through other mechanisms.

Finally, we encourage payers or plans to implement additional, widely used, consensus-based standards identified by other means—such as by HHS for other purposes or through a consensus standards development organization—for additional data in their information systems for which no standard is adopted at 45 CFR part 162, 42 CFR 423.160, or 45 CFR 170.213 to the extent feasible, while maintaining compatibility with the required API technical standards. We also encourage entities to pilot emerging standards identified by HHS, or by a consensus standards development organization through development or approval for trial use, where such a pilot maintains compatibility with the proposed API technical standards. However, MA organizations, state Medicaid and CHIP agencies, Medicaid managed care plans, CHIP managed care entities, and QHPs in FFEs that choose to make non-standardized data available through their APIs would be required to ensure that their API documentation provides sufficient information to an application developer for their applications to handle this information accurately and automatically. We welcome public comment on these proposals.

C. API Standard

In section III.C.2.b. of this proposed rule, we propose to require compliance with the API technical standard proposed by ONC for HHS adoption at 45 CFR 170.215 (published elsewhere in this issue of the **Federal Register**). By requiring compliance with 45 CFR 170.215, we are proposing in section III.C.2.b. of this proposed rule to require use of the foundational Health Level 7 (HL7®) [23] Fast Healthcare Interoperability Resources (FHIR®) standard,[24] several implementation specifications specific to FHIR, and complementary security and app registration protocols (OAuth 2.0 and OpenID Connect Core).

The FHIR standard holds great potential for supporting interoperability and enabling new entrants and competition throughout the health care industry. FHIR leverages modern computing techniques to enable users to access health care ''resources'' over the internet via a standardized RESTful API. Developers can create tools that interact with FHIR APIs to provide actionable data to their stakeholders. In the short time since FHIR was first created, the health care industry has rapidly embraced the standard through substantial investments in industry pilots, specification development, and the deployment of FHIR APIs supporting a variety of business needs. With the exception of the API Resource Collection in Health (ARCH) (proposed by ONC for HHS adoption at 45 CFR 170.215(a)(2)), the API technology standards and implementation specifications proposed at 45 CFR 170.215 (published elsewhere in this issue of the **Federal Register**) are consensus technical standards that, under the National Technology Transfer & Advancement Act of 1995 (Pub. L. 104–113, enacted March 7, 1996) and OMB Circular No. A–119, are, where available and their use not impracticable, preferred for use in government programs over both government-unique standards and standards developed using less rigorous consensus processes.

We note that while all APIs that would be used by software applications to provide consumers access to their electronic health information would be required to adhere to the foundational FHIR standard, and other essential standards such as security protocols applicable to the data exchanged, we do not anticipate that all of the standards, implementation specifications, and

[23] Health Level Seven International (HL7®) is a not-for-profit, ANSI-accredited standards development organization (SDO) focused on developing consensus standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. Learn more at ''About HL7'' web page, last accessed 06/27/2018.)

[24] *https://www.hl7.org/fhir/overview.html.*

protocols proposed at 45 CFR 170.215 will be directly relevant to every use case reflected within the policies proposed in this rule. For example, authenticating end users' identities may not be needed where the information requested and released to an application through the API is limited to information otherwise published, such as provider directory information otherwise required by the programs' regulations to be made widely available.

We note that an API implemented by regulated entities described in section III.C. of this proposed rule is not required to be certified by ONC under the ONC Health IT Certification Program for the related certification criteria. Furthermore, because the data required to be made available by an API as proposed in section III.C. of this proposed rule includes information beyond the USCDI Version 1 data set (proposed by ONC for HHS adoption at 45 CFR 170.213), certification to the ONC certification criteria at 45 CFR 170.215 would not alone be sufficient to ensure the API's capacity to support the full range of data elements required under the proposal in section III.C. of this proposed rule.

Finally, we are aware that the implementation specifications currently proposed by ONC for HHS adoption at 45 CFR 170.215 (published elsewhere in this issue of the **Federal Register**), in complement to the base FHIR foundational standards, leave substantial work to be done by health IT developers and their customers to build and deploy technology to support the proposals described in section III.C.2.b. of this proposed rule. Supplemental technical resources to support efficient and successful implementation of the foundational FHIR standard can be developed by a variety of organizations. However, we recognize that there may be fewer applicable resources to support the development required under this rule. Thus, HHS expects to provide organizations subject to the policies proposed in this proposed rule with technical assistance and subregulatory guidance that incorporates feedback from industry. We recommend readers review ONC's 21st Century Cures Act proposed rule to fully understand the scope and detail of the API standard and content and vocabulary standards proposed by ONC for HHS adoption which apply to the proposals included in this proposed rule. We further recommend readers review the publicly available resources available on the HL7 FHIR standard (*https://www.hl7.org/fhir/overview.html*) and the USCDI Version 1 standard (*https://www.healthit.gov/USCDI*), respectively. These publicly available materials will inform readers understanding of the requirements under this proposed rule and, we expect, will also assist stakeholders in drafting comments submitted within this rulemaking proceeding.

As noted in our proposal in section III.C.2.b. of this proposed rule, we have determined to align our proposal to the types of data, technology use, and available standards that are consistent with an overall HHS approach to support interoperability while mitigating provider and developer burden by requiring compliance with applicable HHS regulations. We hope to see continued innovation and advancement in standards development for identified gaps in health information data classes and data elements, as well as improved bi-directional patient engagement functionalities. For example, we are not proposing to require that organizations subject to the requirements proposed in section III.C. of this proposed rule offer patients or providers the ability through the API to write information directly to patient records held by the organization. However, we hope that organizations and their health IT developers build on the API technology we do propose to require and accelerate innovation responsive to providers' and patients' calls for API write functionality at the fastest pace practicable given the maturity of needed standards. We believe this innovation may be fostered by the concrete steps forward in data exchange and API capabilities we are proposing to require across the significant segment of payers subject to this proposed rule.

D. Updates to Standards

In addition to our efforts to align standards across HHS, we recognize that while we must codify in regulation a specific version of each standard, the need for continually evolving standards development has historically outpaced our ability to amend regulatory text. In order to address how standards development can outpace our rulemaking schedule, we propose in section III.C.2.b. of this proposed rule that regulated entities may use updated versions of required standards if use of the updated version is required by other applicable law.

In addition, under certain circumstances, we propose to allow use of an updated version of a standard if the standard is not prohibited under other applicable law. Where a single standard is updated more than once in a brief period of time and upon review of the standard HHS determines that—to reduce fragmentation and preserve efficacy—only the latest of the updated versions should be used. We will publish subregulatory guidance to that effect.

For content and vocabulary standards at 45 CFR part 162 or 42 CFR 423.160, we propose to allow the use of an updated version of the content or vocabulary standard adopted under this rulemaking, unless the use of the updated version of the standard is prohibited for entities regulated by that part or the program under that section, or prohibited by the Secretary for purposes of these policies or for use in ONC's Health IT Certification Program, or is precluded by other applicable law.

For the content and vocabulary standards proposed by ONC for HHS adoption at 45 CFR 170.213 (USCDI Version 1),[25] as well as for API interoperability standards proposed by ONC for HHS adoption at 45 CFR 170.215 (including HL7 FHIR and other standards discussed above),[26] we propose to allow the use of an updated version of a standard adopted by HHS, provided such updated version has been approved by the National Coordinator through the standards version advancement process described in ONC's 21st Century Cures Act proposed rule (published elsewhere in this issue of the **Federal Register**).

As described in the ONC 21st Century Cures Act proposed rule, under the proposed ONC Standards Version Advancement Process, ONC would allow health IT developers participating in the ONC Health IT certification program to voluntarily use updated versions of adopted standards in their certified Health IT Modules, so long as certain conditions are met. The proposed Standards Version Advancement Process flexibility gives health IT developers the option to avoid unnecessary costs and is expected to help reduce market confusion by enabling certified Health IT Modules to keep pace with standards advancement and market needs. Once a standard has been adopted for use in ONC's Health IT Certification Program through notice and comment rulemaking, ONC would undertake an annual, open and transparent process, including opportunity for public comment, to timely ascertain whether a more recent version of that standard or implementation specification should be approved for developers' voluntary use. ONC expects to use an expanded section

[25] For more information on the USCDI, see *https://www.healthit.gov/USCDI.*

[26] For more information on FHIR, see *https://www.hl7.org/fhir/overview.html.*

of the Interoperability Standards Advisory (ISA) web platform to facilitate the public transparency and engagement process, and to publish each year's final list of National Coordinator-approved advanced versions that health IT developers could elect to use consistent with the Standards Version Advancement Process. (For more detail, please see section VIII.B.5. of ONC's 21st Century Cures Act proposed rule (published elsewhere in this issue of the **Federal Register**).) We believe that permitting the use of updates to standards at 45 CFR 170.213 and 170.215 consistent with the ONC Standards Version Advancement Process will enhance alignment and foster improved interoperability across the health system.

In providing flexibility to the plans and payers that will be required to implement APIs that use the content and vocabulary standards identified in this proposed rule, we also believe it is important to maintain compatibility and avoid a disruption or reduction in data availability to the end user. Entities subject to the proposed regulations seeking to use an updated version of a standard must consider factors such as the impact of differences between standards versions and the potential burden on developers and end users to support transitioning between versions. We expect that these practical considerations to maintain compatibility and avoid disruption will discourage premature use of new versions of a standard.

Therefore, we propose in section III.C.2.b. of this proposed rule that an entity may use an updated version of a required standard so long as use of the updated version does not disrupt an end user's ability to access the data available through the API proposed in section III. of this proposed rule. Entities that would be required to implement an open API under this rulemaking would be free to upgrade to newer versions of the required standards, subject only to those limiting conditions noted here, at any pace they wish. However, they must continue to support connectivity, and make the same data available, for end users using applications that have been built to support only the HHS-adopted version(s) of the API standards.

We welcome public comment on this proposed approach to allow voluntary use of updated versions of these standards.

III. Patient Access Through APIs

A. Background on Medicare Blue Button

We are committed to advancing interoperability, putting patients at the center of their health care, and ensuring they have simple and easy access, without special effort, to their health information. With the establishment of the initial Medicare Blue Button® service in 2010, Medicare beneficiaries became able to download their Part A, Part B, and Part D health care claims data through *MyMedicare.gov* in either PDF or text format. While the original Blue Button effort was a first step towards liberating patient health information, we recognize that significant opportunities remain to modernize access to that health information and the ability to share health information across the health ecosystem. We believe that moving to a system in which patients have access to and use of their health information will empower them to make better informed decisions about their health care. Additionally, interoperability, and the ability for health information systems and software applications to communicate, exchange, and interpret health information in a usable and readable format, is vital to improving health care. Allowing access to health information only through PDF and text format limits the utility and sharing of the health information.

Medicare Blue Button 2.0 is a new, modernized version of the original Blue Button service. It enables beneficiaries to access their Medicare Parts A, B, and D claims data and share that electronic health information through an Application Program Interface (API) with applications, services, and research programs they select. As discussed in more detail in section II.A. of this proposed rule, API technology allows software from different developers to connect with one another and exchange electronic health information in electronic formats that can be more easily compiled and leveraged by patients and their caregivers. Beneficiaries may also select third-party applications to compile and leverage their electronic health information to help them manage their health and engage in a more fully informed way in their health care.

Medicare Blue Button 2.0 is expected to foster increased competition among technology innovators who serve Medicare patients and their caregivers, such as through finding better ways to use claims data to address their health needs. Patients should have the ability to access their health information, in a format of their choosing, to receive a full picture of their health records. API technology can be an effective way to share data because health information from various sources can be retrieved through these secure interfaces and consolidated by a single tool, such as a third-party application chosen by, in the case of Medicare, the beneficiary or their caregiver.

The Medicare Blue Button 2.0 API is also expected to improve the Medicare beneficiary experience by providing beneficiaries secure access to their claims data in a standardized, computable format. We recognize that data security is of the utmost importance and are dedicated to safeguarding patient health information so that only the beneficiary and their authorized personal representative would have the ability to authorize release of their health information through Medicare Blue Button 2.0 to a third-party software application.

Medicare Blue Button 2.0 will provide beneficiaries with a longitudinal view of their Medicare claims data, which can then be combined with other health information within third party applications. One benefit of making records available via an API is that it enables a beneficiary to pull Medicare health information along with other heath information into a single application not dictated by any specific health plan, provider, or portal. APIs allow health information to move through the health ecosystem with the patient and ensure comprehensive and timely information is accessible even if the patient changes health plans, providers, or both over time, facilitating continuity of care.

B. Expanding the Availability of Health Information

1. Benefits of Information Access

We believe there are numerous benefits associated with individuals having simple and easy access to their health care data under a standard that is widely used. Claims and encounter data, used in conjunction with EHR data, can offer a broader and more holistic understanding of an individual's interactions with the health care system than EHR data alone. For example, inconsistent benefit utilization patterns in an individual's claims data, such as a failure to fill a prescription or receive recommended therapies, can indicate that the individual has had difficulty adhering to a treatment regimen and may require less expensive prescription drugs or therapies, additional explanation about the severity of their condition, or other types of assistance. Identifying and

finding opportunities to address the individual's non-adherence to a care plan are critical to keeping people with chronic conditions healthy and engaged so they can avoid hospitalizations. While a health plan can use claims and encounter data to help it identify which enrollees could benefit from an assessment of why they are not filling their prescriptions or who might be at risk for particular problems, putting this information into the hands of the individual's chosen care provider—such as the doctor or nurse practitioner prescribing the medications or the pharmacist who fills the prescriptions—helps them to engage the patient in shared decision making that can help address some of the reasons the individual might not be willing or able to take medications as prescribed. By authorizing their providers to access the same information through the open API, individuals can further facilitate communication with their care teams. Enabling the provider to integrate claims and encounter information with EHR data gives the provider the ability to use the combined information, with relevant clinical decision support tools, as part of normal care delivery in a less burdensome way, leading to improved care. This may be particularly important during times of system surge, for example, in the event of an event that generates a large and sudden demand for health services, when access to such information may help to inform patient triage, transfer, and care decisions.

Further, consumers who have immediate electronic access to their health information are empowered to make more informed decisions when discussing their health needs with providers, or when considering changing to a different health plan. In many cases, claims and encounter data can provide a more holistic and comprehensive view of a patient's care history than EHR data alone. Whereas EHR data is frequently locked in closed, disparate health systems, care and treatment information in the form of claims and encounter data is comprehensively combined in a patient's claims and billing history. Currently, not all beneficiaries enrolled in MA plans have immediate electronic access to their claims and encounter data and those who do have it, cannot easily share it with providers or others. The same is true of Medicaid beneficiaries and CHIP enrollees, whether enrolled in FFS or managed care programs, and enrollees in QHPs in FFEs. As industries outside of health care continue to integrate multiple sources of data to understand and predict their consumers' needs, we believe it is important to position MA organizations, Medicaid and CHIP managed care entities, and QHP issuers in FFEs to do the same to encourage competition, innovation, and value. Further, we believe that beneficiaries in Medicaid FFS programs administered by state Medicaid agencies and CHIP enrollees in both FFS and managed care should benefit from similar advances and the benefits of innovation and value.

CMS has programmatic authority over MA organizations, Medicaid programs (both FFS and managed care), CHIP (including FFS and managed care), and QHP issuers in FFEs. This proposed rule seeks to leverage that CMS authority to make claims and encounter data available to patients in these programs along with other plan data (such as provider directory data) as detailed in sections III.C. and IV. of this proposed rule. We propose that regulated entities make this data available in a standardized format and through a specific technological means so that third parties can develop and make available applications that make the data available for patient use in a convenient and timely manner. Our proposal would require compliance with specific regulations regarding interoperability standards adopted by the Secretary in implementing and complying with the proposed requirement to use an API to make this data available. We are proposing to require compliance with 45 CFR 170.215 to require the API technical standards that ONC is proposing for HHS adoption in its 21st Century Cures Act proposed rule (published elsewhere in this issue of the **Federal Register**). We are also proposing to require that the data elements made available through the proposed API technology must be formatted and presented in accordance with applicable content and vocabulary standards as described in section II. of this proposed rule. This means that the software receiving and using the data can readily consume the data to support consumer-friendly display and other functionalities.

Ultimately, the goal of this proposal is to require that patient data be made available in a standardized format through an API, so that third parties can develop and offer applications that make the data available in a convenient and timely manner for enrollees and beneficiaries in MA plans, Medicaid and CHIP FFS and managed care delivery systems, and FFEs that are specified in our proposal as detailed below.

2. Alignment With the HIPAA Right of Access

The HIPAA Privacy Rule, at 45 CFR 164.524, provides that individuals have a right of access to inspect and obtain a copy of PHI, defined at 45 CFR 160.103, about them that is maintained by a health plan or covered health care provider in a designated record set, defined at 45 CFR 164.501. The right of access also provides individuals with the right to initiate disclosures to third parties.

Software applications using the API proposed in 42 CFR 422.119, 431.60, 438.242(b)(6), 457.730, 457.1233(d)(2), and 45 CFR 156.221 would provide an additional mechanism through which the individuals in that coverage who so choose can exercise the HIPAA right of access to their PHI, by giving them a simple and easy electronic way to request, receive, and share data that they want and need, including with a designated third party. However, as discussed in section II of this proposed rule, due to limitations in current availability of interoperability standards for some types of data and patient's rights to be granted access in the form and manner of their own choosing, the API requirement may not be sufficient to support access to all of the health information subject to the HIPAA right of access because it may not all be transferable through the API.

C. Open API Proposal for MA, Medicaid, CHIP, and QHP Issuers in FFEs

1. Introduction

We are proposing to add new provisions at 42 CFR 422.119, 431.60, 438.242(b)(6), 457.730, 457.1233(d) and 45 CFR 156.221, that would, respectively, require MA organizations, state Medicaid FFS programs, Medicaid managed care plans, CHIP FFS programs, CHIP managed care entities, and QHP issuers in FFEs (excluding issuers of SADPs) to implement, test, and monitor an openly-published API that is accessible to third-party applications and developers. We note that states with CHIPs are not required to operate FFS systems and that some states' CHIPs are exclusively operated by managed care entities. We do not intend to require CHIPs that do not operate a FFS program to establish an API; rather, these states may rely on their contracted plans, referred to throughout this proposed rule as CHIP managed care entities, to set up such a system.

The API would allow enrollees and beneficiaries of MA organizations, Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP

managed care entities, and QHP issuers in FFEs to exercise electronically their HIPAA right of access to certain health information specific to their plan, through the use of common technologies and without special effort. Common technologies, for purposes of our proposal, are those that are widely used and readily available, such as computers, smartphones or tablets.

We are proposing that the API would be required to meet certain interoperability standards, consistent with the API technical standards proposed by ONC for HHS adoption in its proposed rule (published elsewhere in this issue of the **Federal Register**), as well as to require the use of content and vocabulary standards adopted by HHS and that the use of these standards would be applicable across the specific entities subject to proposed 42 CFR 422.119, 431.60, 438.242(b)(6), 457.730, and 457.1233(d), and 45 CFR 156.221. In this context, these standards are critical to ensure that enrollees of those plans and programs have electronic access to their health information in interoperable form and that access to their health information and information about their coverage are not obstructed by, or confined to, certain propriety systems.

Under our proposal, the scope and volume of the information to be provided or made accessible through the open API would include: Adjudicated claims (including cost); encounters with capitated providers; provider remittances; enrollee cost-sharing; and clinical data, including laboratory results (where available). We propose that these programs and organizations, with the exception of the QHP issuers in FFEs, would also be required to make information regarding provider directories and formularies available through the open API. Sections 1852(c), 1932(a)(5), and 2103(f)(3) of the Act require that MA organizations and Medicaid MCOs, and CHIP managed care entities provide basic information to their enrollees on how to get covered benefits in the plan and to facilitate decision making about plan choice, providers, and benefits. These statutory provisions indicate information enrollees could use to make decisions about their health care. The API proposals at 42 CFR 422.119(a), 438.242(b)(6), and 457.1233(d) support and complement existing implementation of these provisions in a robust and modern way. We believe the health information that would be available through the proposed API would greatly supplement the benefit, provider directory, and, if applicable, formulary information from states and managed care plans by providing important details and context, thus enabling enrollees to make more informed, proactive decisions.

Additionally, we believe that since most of the information required to be provided by these statutory sections of the Act, such as the provider directory, is currently accessible to enrollees and potential enrollees electronically online, making such standardized health information available through the proposed API could allow easy integration for use by more enrollees. Further, the proposal would enable these enrollees to more easily share their information with providers, family, caregivers, and others. As a general matter, providing important details and context to patients gives them more visibility into their treatment record through adjudicated claims, allowing them to be true partners in their health care. This goal is related to the disclosure requirements in sections 1852, 1932 and 2103 of the Act and our proposal furthers each.

We also believe the proposed API allows for the administration of more efficient and effective Medicaid and CHIP programs by taking advantage of commonly used methods of information sharing and data standardization. Consumers routinely perform many daily tasks on their mobile phones—banking, shopping, paying bills, scheduling—using secure applications. We believe that obtaining their health information should be just as easy, convenient, and user-friendly. Our proposal is a step toward that vision for enrollees in MA plans, Medicaid FFS and managed care programs, CHIP FFS programs and managed care entities, and QHPs in FFEs. Finally, our proposal includes a number of parameters and standards for the API and for adopting, implementing, testing, and monitoring the API; the specific pieces of our proposal are addressed in turn in sections III.C.2 of this proposed rule.

2. The Open API Proposal

This section outlines the components of the open API proposal. Specifically, this section will discuss:

- Authority to require implementation of an open API;
- The API technical standard and content and vocabulary standards;
- Data Required To Be Available Through the Open API & Timeframes for Data Availability;
- Documentation Requirements for APIs;
- Routine Testing and Monitoring of Open APIs;
- Compliance with Existing Privacy and Security Requirements;
- Denial or Discontinuation of Access to the API;
- Enrollee and Beneficiary Resources Regarding Privacy and Security;
- Exceptions or Provisions Specific to Certain Programs or Sub-Programs;
- Applicability and Timing; and
- Request for Information on Information Sharing Between Payers and Providers Through APIs.

We are proposing nearly identical language for the regulations requiring open APIs at 42 CFR 422.119; 431.60, and 457.730 and 45 CFR 156.221 for MA organizations, Medicaid state agencies, state CHIP agencies, and QHPs in FFEs; Medicaid managed care plans would be required at 42 CFR 438.242(b)(6), to comply with the requirement at 42 CFR 431.60, and CHIP managed care entities would be required by 42 CFR 457.1233(d)(2) to comply with the requirement at 42 CFR 457.730. As discussed in detail in this proposed rule, we are proposing similar if not identical requirements for these various entities to establish and maintain an open API, make specified data available through that API, disclose API documentation, provide access to the API, and make resources available to enrollees. We believe that such nearly identical text is appropriate here as the reasons and need for the proposal and the associated requirements are the same across these programs. Except as noted below with regard to specific proposals, we intend to interpret and apply the regulations proposed in this section, III.C. of this proposed rule, similarly and starting with similar text is an important step to communicate that to the applicable entities that would be required to comply.

In paragraph (a) of each of the proposed regulations, we propose that the regulated entity (that is, the MA organization, the State Medicaid or CHIP agency, the Medicaid managed care plan, the CHIP managed care entity or the QHP in an FFE, as applicable) would be required to implement and maintain an open API that permits third-party applications to retrieve, with the approval and at the direction of the individual beneficiary, data specified in paragraph (b) of each regulation through the use of common technologies and without special effort from the beneficiary. By ''common technologies and without special effort'' by the enrollee, we mean use of common consumer technologies, like smart phones, home computers, laptops or tablets, to request, receive, use and approve transfer of the data that would be available through the open API technology. By ''without special effort,'' we codify our expectation that third-

party software, as well as proprietary applications and web portals operated by the payer could be used to connect to the API and provide access to the data to the enrollee. In our proposed regulations, we address the data that must be made available through the API in paragraph (b); the regulation regarding the technical standards for the API and the data it contains in paragraph (c); the documentation requirements for the API in paragraph (d); explicit authority for the payer regulated under each regulation to deny or discontinue access to the API in paragraph (e); and requirements for posting information about resources on security and privacy for beneficiaries in paragraphs (f) or (g). Additional requirements specific to each program, discussed in sections IV. and V. of this proposed rule, are also included in some of the regulations that address the API.

We solicit comment on our use of virtually identical language in these regulations and our overall proposal to require implementation and maintenance of an open API.

a. Authority To Require Implementation of an Open API

Our proposal would apply to MA organizations, Medicaid state agencies and managed care plans, state CHIP agencies and managed care entities, and QHP issuers in FFEs. We note that our proposal for Medicaid managed care plans, at 42 CFR 438.242(b)(6), would require MCOs, PIHPs, and PAHPs to comply with the regulation that we are proposing for Medicaid state agencies at 42 CFR 431.60 as if that regulation applied to the Medicaid managed care plan. Similarly, we intend for CHIP managed care entities to comply with the requirements we propose at 42 CFR 457.730 via the regulations proposed at 42 CFR 457.1233(d)(2). We propose to structure the regulations this way to avoid ambiguity and to ensure that this API proposal would result in consistent access to information for Medicaid beneficiaries and CHIP enrollees, regardless of whether they are in a FFS delivery system administered by the state or in a managed care delivery system. CHIP currently adopts the Medicaid requirements at 42 CFR 438.242 in whole. We propose revisions to 42 CFR 457.1233(d)(1) to indicate CHIP's continued adoption of 42 CFR 438.242(a), (b)(1) through (5), (c), (d), and (e), while proposing specific text for CHIP managed care entities to comply with the regulations proposed at 42 CFR 457.1233(d)(2) in lieu of the proposed Medicaid revision, which would add 42 CFR 438.242(b)(6). In our discussion of the specifics of this proposal and how we propose to codify it at 42 CFR 422.119, 431.60, 457.730, and 45 CFR 156.221, we refer only generally to 42 CFR 438.242(b)(6) and 457.1233(d)(2) for this reason.

(1) Medicare Advantage

Sections 1856(b) and 1857(e) of the Act provide CMS with the authority to add standards and requirements for MA organizations that the Secretary finds necessary and appropriate and not inconsistent with Part C of the Medicare statute; section 1852(c) of the Act requires disclosure by MA organizations of specific information about the plan, covered benefits, and the network of providers; section 1852(h) of the Act requires MA organizations to provide their enrollees with timely access to medical records and health information insofar as MA organizations maintain such information. As technology evolves to allow for faster, more efficient methods of information transfer, so do expectations as to what is generally considered ''timely.'' Currently, consumers across public and private sectors have become increasingly accustomed to accessing a broad range of personal records, such as bank statements, credit scores, and voter registrations, immediately through electronic means and with updates received in near real time. Thus, we believe that in order to align our standards with 21st century demands, we must take steps for MA enrollees to have immediate, electronic access to their health information and plan information. The proposed requirements in this rule are intended to achieve this goal.

We believe that the scope of the information that would be made available through an API under this proposal (described in section III. of this proposed rule) is consistent with the access and disclosure requirements in section 1852 of the Act, and we rely on our authority in sections 1856(b) and 1857(e) of the Act, which provide CMS with the authority to add standards and requirements for MA organizations, to require MA organizations to make specific types of information, at minimum, accessible through an open API and require timeframes for update cycles. Throughout this section III.C. of this proposed rule, we explain how and why the open API proposal is necessary and appropriate for MA organizations and the MA program; the goals and purposes of achieving interoperability for the health care system as a whole are equally applicable to MA organizations and their enrollees; thus, the discussion in section II of this proposed rule serves to provide further explanation as to how an open API proposal is necessary and appropriate in the MA program. Further, having easy access to their claims, encounter, and other health information would also facilitate beneficiaries' ability to detect and report fraud, waste, and abuse—a critical component of an effective program.

To the extent necessary, we also rely on section 1860D–12(b)(3) of the Act to add provisions specific to the Part D benefit offered by certain MA organizations. For MA organizations that offer MA Prescription Drug plans, we are proposing requirements in 42 CFR 422.119(b)(2) regarding electronic health information for Part D coverage. That aspect of our proposal is also supported by the disclosure requirements imposed under section 1860D–4(a) of the Act, which requires Part D claims information, pharmacy directory information, and formulary information to be disclosed to enrollees.

(2) Medicaid and CHIP

We are proposing new provisions at 42 CFR 431.60(a), 457.730, 438.242(b)(6), and 457.1233(d)(2) that would require states administering Medicaid FFS or CHIP FFS, Medicaid managed care plans, and CHIP managed care entities to implement an open API that permits third-party applications authorized by the beneficiary or enrollee to retrieve certain standardized data. This proposed requirement would provide Medicaid beneficiaries' and CHIP enrollees simple and easy access to their information through common technologies, such as smartphones, tablets, or laptop computers, and without special effort on the part of the user.

For Medicaid, we are proposing these new requirements under the authority in section 1902(a)(4) of the Act, which requires that a state Medicaid plan for medical assistance provide such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the plan and section 1902(a)(19) of the Act, which requires that care and services be provided in a manner consistent with simplicity of administration and the best interests of the recipients. For CHIP, we propose these requirements under the authority in section 2101(a) of the Act, which sets forth that the purpose of title XXI is to provide funds to states to provide child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage. Together these provide us with authority (in conjunction with our

delegation of authority from the Secretary) to adopt requirements for Medicaid and CHIP that are necessary to ensure the provision of quality care in an efficient and cost-effective way, consistent with simplicity of administration and the best interest of the beneficiary.

We believe that requiring state Medicaid and CHIP agencies and managed care plans/entities to take steps to make Medicaid beneficiaries' and CHIP enrollees' claims, encounters, and other health information available through interoperable technology will ultimately lead to these enrollees accessing that information in a convenient, timely, and portable way, which is essential for these programs to be effectively and efficiently administered in the best interests of beneficiaries. Further, as noted in this proposed rule, there are independent statutory provisions that require the disclosure and delivery of information to Medicaid beneficiaries and CHIP enrollees; this proposal assists in the implementation of those requirements in a way that is appropriate and necessary in the 21st century. We believe making this information available in this format would result in better health outcomes and patient satisfaction and improve the cost effectiveness of the entire health care system, including Medicaid and CHIP. Having easy access to their claims, encounter, and other health information would also facilitate beneficiaries' ability to detect and report fraud, waste, and abuse—a critical component of an effective program.

As technology has advanced, we have encouraged states, health plans, and providers to adopt various forms of technology to improve the accurate and timely exchange of standardized health care information. This proposal would move Medicaid and CHIP programs in the direction of enabling better information access by Medicaid beneficiaries and CHIP enrollees, which would make them active partners in their health care through the exchange of electronic health information by easily monitoring and sharing their data. By requiring that certain information be available in and through standardized formats and technologies, our proposal moves these programs toward interoperability, which is key for data sharing and access, and ultimately, improved health outcomes. As an additional note, states will be expected to implement the CHIP provisions using CHIP administrative funding, which is limited under section 2105(a)(1)(D)(v) and 2105(c)(2)(A) of the Act to 10 percent of a State's total annual CHIP expenditures.

(3) Qualified Health Plan Issuers in Federally-Facilitated Exchanges

We propose a new QHP minimum certification standard at 45 CFR 156.221(a) that would require QHP issuers in FFEs, not including SADPs, to implement an open API that permits third-party applications, with the approval and at the direction of the individual enrollee, to retrieve standardized data concerning adjudicated claims (including cost), encounters with capitated providers, and provider remittances, enrollee cost-sharing, and clinical data, including laboratory results (where available). We are also proposing to require that the data be made available to QHP enrollees through common technologies, such as smartphones or tablets, and without special effort from enrollees.

We are proposing these new requirements under our authority in section 1311(e)(1)(B) of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–148, enacted March 23, 2010, and Pub. L. 111–152, enacted March 30, 2010, respectively) (collectively referred to as the Affordable Care Act), which affords the Exchanges the discretion to certify QHPs that are in the best interests of qualified individuals and qualified employers. Specifically, section 1311(e) of the Affordable Care Act authorizes Exchanges to certify QHPs that meet the QHP certification standards established by the Secretary, and if the Exchange determines that making available such health plan through such Exchange is in the interests of qualified individuals and qualified employers in the state or states in which such Exchange operates.

We believe there are numerous benefits associated with individuals having access to their health plan data that is built upon widely used standards. The ability to easily obtain, use, and share claims, encounter, and other health data enables enrollees to more effectively and easily use the health care system. For example, by being able to easily access a comprehensive list of their adjudicated claims, the plan enrollee can ensure their providers know what services have already been received, avoid receiving duplicate services; and verify when prescriptions were filled. We believe these types of activities would result in better health outcomes and enrollee satisfaction and improve the cost effectiveness of the entire health care system. Having simple and easy access, without special effort, to their health information, including cost and payment information, also facilitates enrollees' ability to detect and report fraud, waste, and abuse—a critical component of an effective program. Existing and emerging technologies provide a path to make information and resources for health and health care management universal, integrated, equitable, accessible to all, and personally relevant. Therefore, we believe generally certifying only health plans that make enrollees' health information available to them in a convenient, timely, and portable way is in the interests of qualified individuals and qualified employers in the state or states in which an FFE operates. We encourage SBEs to consider whether a similar requirement should be applicable to QHP issuers participating in their Exchange.

b. API Technical Standard and Content and Vocabulary Standards

We propose to require compliance with proposed 45 CFR 170.215 at 42 CFR 422.119(a) and (c), 431.60(a) and (c) and 457.730(a) and (c), 438.242(b)(6) and 457.1233(d)(2), and 45 CFR 156.221(a) and (c), so that MA organizations, Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs implement open API technology conformant with the proposed API technical standards (published elsewhere in this issue of the **Federal Register**) (see also section II.A.3. of this proposed rule). We further propose to require compliance with the regulations regarding the following content and vocabulary standards for data available through the API, where applicable to the data type or data element, unless an alternate standard is required by other applicable law: standards adopted at 45 CFR part 162 and 42 CFR 423.160; and standards proposed by ONC for adoption by HHS at 45 CFR 170.213 (USCDI Version 1). See section II.A.3. of this proposed rule for further information about our proposals regarding how entities subject to this rule would be required to utilize these standards. We are proposing that both the API technical standard and the content and vocabulary standards would be required across the MA program, Medicaid program, and CHIP, and by QHP issuers in FFEs (not including issuers of SADPs).

Further, with the new proposed requirements to implement and maintain an API at 42 CFR 422.119(a), 431.60(a), and 457.730(a), we are proposing corresponding requirements at proposed 42 CFR 422.119(c) for MA

plans, 431.60(c) for Medicaid FFS programs, and 457.730(c) for CHIP FFS programs implementing the proposed API technology. In proposed paragraphs 42 CFR 422.119(c), 431.60(c), 457.730(c), MA plans and the state Medicaid or CHIP (for CHIP agencies that operate FFS systems) agency would be required to implement API technology conformant with the standards proposed by ONC for HHS adoption at 45 CFR 170.215; for data available through the API, to use content and vocabulary standards adopted at 45 CFR part 162 and 42 CFR 423.160, and proposed for adoption at 45 CFR 170.213; and to maintain and use the technology in compliance with applicable law, including but not limited to 45 CFR parts 162, 42 CFR part 2, and the HIPAA Privacy and Security Rules.

We similarly propose at 45 CFR 156.221(c) that QHP issuers in FFEs must implement API technology conformant with the API technical standards proposed by ONC for HHS adoption at 45 CFR 170.215; for data available through the API, use content and vocabulary standards adopted at 45 CFR part 162 and 42 CFR 423.160, and proposed for adoption at 45 CFR 170.213; and maintain and use the technology in compliance with applicable law, including but not limited to 45 CFR part 162, 42 CFR part 2, and the HIPAA Privacy and Security Rules.

We believe that these proposals would serve to create a health care information ecosystem that allows and encourages the health care market to tailor products and services to better serve and compete for patients, thereby increasing quality, decreasing costs, and empowering patients with information that helps them live better, healthier lives. Additionally, under these proposals, clinicians would be able to review information on their patient's current prescriptions and services received by the enrollee on the enrollee's smartphone. Also, the enrollee could allow clinicians to access such information by sharing data received through the API with the clinician's EHR system—by forwarding the information once the enrollee receives it or by authorizing release of the data through the API directly to the clinician's EHR system.

We also encourage payers to consider using the proposed API infrastructure as a means to exchange PHI for other health care purposes, such as to health care providers for treatment purposes. Sharing interoperable information directly with the enrollee's health care provider's EHR in advance of a patient visit would save time during appointments and ultimately improve the quality of care delivered to patients. Most clinicians and patients have access to the internet, providing many access points for viewing health information over secure connections. We believe that these proposed requirements would significantly improve patients' experiences by providing a mechanism through which they can access their data in a standardized, computable, and digital format in alignment with other public and private health care entities. We also believe that these proposals are designed to empower patients to have simple and easy access to their data in a usable digital format, and therefore, can empower them to decide how their health information is going to be used. However, we remind payers that this proposed regulation regarding the API would not lower or change their obligations as HIPAA covered entities to comply with regulations regarding standard transactions in 45 CFR part 162.

As discussed in section II.A.3. of this proposed rule, we recognize that while we must codify in regulation a specific version of each standard, the need for continually evolving standards development has historically outpaced our ability to amend regulations. To address how standards development can outpace our rulemaking schedule, we offer several proposals. We propose that regulated entities may use an updated version of a standard where required by other applicable law. We also propose that regulated entities may use an updated version of the standard where not prohibited by other applicable law, under certain circumstances. First, we propose to allow the use of an updated version of content or vocabulary standards adopted at 45 CFR part 162 or 42 CFR 423.160, unless the use of the updated version of the standard is prohibited for entities regulated by that part or the program under that section, is prohibited by the Secretary for purposes of these policies, is prohibited for use in ONC's Health IT Certification Program, or is prohibited by other applicable law.

Second, for the content and vocabulary standards proposed by ONC for HHS adoption at 45 CFR 170.213 (USCDI Version 1), as well as for API interoperability standards proposed by ONC for HHS adoption at 45 CFR 170.215 (including HL7 FHIR and other standards discussed above), we propose to allow the use of an updated version, provided such updated version has been approved by the National Coordinator through the Standards Version Advancement Process described in ONC's 21st Century Cures Act proposed rule (published elsewhere in this issue of the **Federal Register**).

Finally, we propose that use of an updated standard by a payer that is subject to these proposed regulations must not disrupt an end user's ability to access the data available through the API proposed in section III. of this proposed rule using an application that was designed to work with an API that conforms to the API standard proposed under ONC's 21st Century Cures Act proposed rule (published elsewhere in this issue of the **Federal Register**). Entities that would be required to implement an open API under this rulemaking would be free to upgrade to newer versions of the required standards, subject only to those limiting conditions noted here, and at any pace they wish. However, they must continue to support connectivity and make the same data available to applications that have been built to support only the adopted version(s) of the API standards. For further discussion of these proposals, see section II.A.3.D. of this proposed rule.

c. Data Required To Be Available Through the Open API & Timeframes for Data Availability

We propose the content that must be accessible for each enrollee of an entity subject to our open API proposal as set out at paragraph (b) of 42 CFR 422.119, 431.60, and 457.730 and 45 CFR 156.221; as noted previously, the regulations for Medicaid managed care plans and CHIP managed care entities cross-reference and incorporate the regulations we propose for Medicaid and CHIP programs. We note that the types of content proposed here would represent the minimum threshold for compliance; at their discretion, MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs would have the option to use the API required by this proposed rule to make additional types of health information or plan information available, exceeding these minimum requirements.

We request comment on the data proposed to be made available as detailed in the subsections below, the appropriateness of the proposed timeframes, and suggestions for alternative timeframes that consider the utility to the beneficiary, as well as challenges that the proposed timeframe may create for the entities that would have to comply.

(1) Patient Claims and Encounter Data

We propose that MA organizations, Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs, permit third-party applications to retrieve, with the approval of an enrollee, certain specific data: adjudicated claims data, including provider remittances and beneficiary or enrollee cost-sharing data; encounters from capitated providers; and clinical data, including laboratory results (but only if managed by the payer). Adjudicated claims data would include on approved and denied claims; under this proposal, adjudicated claims data includes that for which the plan has made an initial payment decision even when the period during which an enrollee can file an appeal is still in effect, or when the enrollee has filed an appeal and is awaiting a reconsideration decision. We specifically request comments from plans regarding the feasibility of including such claims data, including any possible timing issues. In addition, the open APIs required for these entities must make available formulary information (for MA–PD plans) or information about covered outpatient drugs and preferred drug lists (for state Medicaid and CHIP agencies, Medicaid managed care plans and CHIP managed care entities).

Our proposal includes timeframe requirements for making these various categories of data available through the open API. For MA organizations, proposed 42 CFR 422.119(b)(1)(i), (1)(ii), and (2)(i) would require open API access to all claims activity pertaining to adjudicated claims (including cost) and encounter data for benefits covered by the plan (that is, Medicare Part A and Part B items and services, Part D prescription drugs if covered by the MA plan, and any supplemental benefits) no later than one (1) business day after a claim is adjudicated or the encounter data is received by the MA organization. For clinical data, including laboratory results, MA organizations that manage such data would be required under 42 CFR 422.119(b)(1)(iv) to provide access through the open API to that data no later than one business day after it is received by the MA plan. For Medicaid state agencies and managed care plans, claims data, encounter data, and clinical data, including laboratory results (if available) would be required (specifically at 42 CFR 431.60(b)(1),(2), and (4)) through the API no later than one business day after the claim is processed or the data is received. For State Medicaid agencies in connection with the FFS program, the API would have to include all claims data concerning adjudicated claims and standardized encounter data from providers (other than MCOs, PIHPs or PAHPs) that are paid using capitated payments. The requirement for Medicaid managed care plans to provide encounter data is specified at 42 CFR 438.242(b)(6)(i); encounter data would include any data from subcontractors and providers compensated by the managed care plan on the basis of capitation payments, such as behavioral health organizations, dental management organizations, and pharmacy benefit managers. The API of Medicaid managed care plans would have to include all claims and encounter data would be included regardless if it is adjudicated or generated by the managed care plan itself, subcontractor, or provider compensated on the basis of capitation payments. All data would need to be obtained in a timely manner to comply with these proposed requirements.

For CHIP agencies and managed care entities, claims data, encounter data, and reports of lab test results (if available) would be required (specifically at 42 CFR 457.730(b)(1),(2), and (4)) through the API as soon as possible but no later than one business day. The proposal for CHIP state agencies (regarding FFS programs) and CHIP managed care entities is identical to the proposal for Medicaid State agencies (regarding FFS programs) and Medicaid managed care plans. For QHP issuers in FFEs, our proposed regulation at 45 CFR 156.221(b) would require claims, encounter, and lab data to be available within one business day of adjudication and receipt, respectively.

These proposed timeframes would ensure that data provided through the API would be the most current data available, which may be critical if the data is provided by an enrollee to his or her health care provider to use in making clinical decisions. Under our proposal, the claims and encounter data to be disclosed should include information such as enrollee identifiers, dates of service, payment information (provider remittance if applicable and available), and enrollee cost-sharing. The ability for enrollees—created and facilitated by the API required under our proposal—to access this information electronically would make it easier for them to take it with them as they move from payer to payer or among providers across the care continuum.

Regarding the provision of standardized encounter data through the API within one (1) business day of the receiving the data, we note that this proposal would mean that a payer must rely on capitated providers submitting their encounter data in a timely manner to ensure that patients receive a timely and complete set of data. To the extent providers do not submit in a timely manner, there would be a delay in patients having access to their data. We recommend that MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs that would need this information in order to meet the proposed API requirements should consider whether their contracts with network providers should include timing requirements for the submission of encounter data and claims so that the payer can comply with the API requirements. For Medicaid and CHIP FFS programs, we encourage states to consider other means to ensure that necessary encounter data from providers is also provided on a timely basis.

We note that the data for claims and remittances that would be available through the API is much of the same data that is required for the ASC X12 837, ASC X12 835, and ASC X12 863 standards which are required for certain transactions between certain entities under 45 CFR 162.1102, 162.1602 and 162.1603, as well as the Part D eRx transaction standards that use for conveying prescription and prescription-related information between Part D plans, providers, and pharmacies as specified in 42 CFR 423.160. As most claims are submitted to payers electronically utilizing these industry standard transaction types, we believe this maximizes efficiency and reduces programming burden. As noted previously, our proposed regulation for Medicaid managed care plans at 42 CFR 438.242(b)(6) and for CHIP managed care entities at 42 CFR 457.1233(d)(2) would require MCOs, PIHPs, and PAHPs to comply with the same standard transaction types.

Specifically regarding QHP issuers in FFEs, in 45 CFR 156.221(b)(1)(i) and (ii), we propose to require that QHP issuers participating in an FFE make available through the API standardized data concerning adjudicated claims (including cost) and encounters with capitated providers. Under proposed paragraph (b)(1)(i), QHP issuers in FFEs would be required to make available standardized adjudicated claim, provider remittance, and enrollee cost-sharing data through the API within one (1) business day after the claim is processed. Under proposed paragraph (b)(1)(ii), QHP issuers in FFEs would be required to provide standardized encounter data through the API within one (1) business day of the issuer receiving the data.

We are also considering requiring the encounter data to be available through the API within a certain period after the encounter, within one (1) business day after the encounter data is received. We seek comment on what a reasonable period from the encounter date would be for us to consider as part of future rulemaking. In addition, we solicit comment on our authority to require MA organizations, States (for FFS Medicaid programs and CHIP), Medicaid and CHIP managed care plans, and QHPs in the FFEs to require submission of such data on a particular timeframe.

(2) Provider Directory Data

We are also proposing at 42 CFR 422.119(b)(1)(iii), 431.60(b)(3), 438.242(b)(6)(ii), 457.730(b)(3), and 457.1233(d)(2)(ii) that the required API make available provider directory data, including updates to such data. Our proposal at 45 CFR 156.221 would not require QHP issuers to permit third-party retrieval of provider directory and preferred drug list information because such information is already required to be provided by QHPs in FFEs.

For MA organizations, at proposed 42 CFR 422.119(b)(1)(iii), we propose to specify that MA organizations make specific provider directory information for their network of contracted providers accessible through their APIs: The names of providers; addresses; phone numbers; and specialty. This information is the same information MA organizations are already required to disclose to their enrollees under 42 CFR 422.111(b)(3) and make available online under 42 CFR 422.111(h)(2)(ii). MA organizations would be required to ensure the availability of this information through their APIs for all MA plans. Including this information in an open API allows non- MA third-party applications to consume, aggregate, and display plan data in different contexts, allowing patients to understand and compare plan information in a way that can best serve their individual needs. MA plans would be required to update provider directory information available through the API no later than 30 calendar days after changes to the provider directory are made. In addition, we are adding a new MA contract requirement at 42 CFR 422.504(a)(18) specifying that MA organizations must comply with the requirement for access to health data and plan information under 42 CFR 422.119.

Under proposed 42 CFR 431.60(b)(3) and 457.730(b)(3), state Medicaid and CHIP agencies respectively would be required to make provider directory information available through the API, including updated provider information no later than 30 calendar days after the state receives updated provider information. As noted previously, our proposed regulation for Medicaid managed care plans at 42 CFR 438.242(b)(6) and for CHIP managed care entities at 42 CFR 457.1233(d)(2) would require MCOs, PIHPs, and PAHPs to comply with the same standard, with the addition of specific provider directory information as noted in 42 CFR 438.242(b)(6)(ii) and 457.1233(d)(2)(ii). For Medicaid managed care plans and CHIP managed care entities, the provider directory information available through the API must include all information that is specified in 42 CFR 438.10(h)(1) for disclosure to managed care enrollees. We note that we have proposed that the API be updated with new provider directory information within 30 calendar days from when the updated information is received by the State (or the managed care plan under 42 CFR 438.242(b)(6) and 457.1233(d)(2)) to be consistent with existing Medicaid managed care rules at 42 CFR 438.10(h)(3). We propose that the API implemented by the State Medicaid agency would include the data elements specified for disclosure by Medicaid state agencies in section 1902(a)(83) of the Act; we propose in 42 CFR 438.242(b)(6)(ii) that the API implemented by Medicaid managed care plans would have the data elements specified for disclosure at 42 CFR 438.10(h)(1). For CHIP agencies that operate FFS systems and CHIP managed care entities at 42 CFR 457.730(b)(3) and 457.1233(d)(2)(ii), respectively, we have also proposed 30 calendar days.

We are not proposing a similar requirement for QHP issuers in FFEs. These issuers are already required, under 45 CFR 156.230(c) and implementing guidance, to make provider directory information accessible in a machine-readable format. Because this information is already highly accessible in this format, we do not believe the benefits of making it also available through an open API outweigh the burden for QHP issuers in FFEs. However, we seek comment as to whether this same requirement should apply to QHP issuers, or if such a requirement would be overly burdensome for them.

We request comment on these proposals.

(3) Clinical Data Including Laboratory Results

Regarding the provision of clinical data, including laboratory results, we propose at 42 CFR 422.119(b)(1)(iv) that MA organizations make clinical data, such as laboratory test results available through the API if the MA organization manages such data. Because we propose in paragraph (c) that the USCDI standard, proposed by ONC for HHS adoption at 45 CFR 170.213, be used as the content and vocabulary standard for this clinical data as provided in the API, we intend our proposal to mean that the data required under paragraph (b)(1)(iv) be the same as the data that is specified in that content and vocabulary standard. In effect, we are proposing any clinical data included in the USCDI standard, proposed by ONC for HHS adoption at 45 CFR 170.213, be available through the API if such data is managed by the MA organization. We recognize that some MA organizations receive this information regularly or as a part of their contracted arrangements for health services, but that not all MA organizations do. Therefore, this proposed requirement applies to MA organizations, regardless of the type of MA plan offered by the MA organization, but only under circumstances when the MA organization receives and maintains this data as a part of its normal operations. This proposed requirement aligns with existing regulations at 42 CFR 422.118, which require MA organizations to disclose to individual enrollees any medical records or other health or enrollment information the MA organizations maintain with respect to their enrollees. We propose that this data be available in the API no later than 1 business day from its receipt by the MA organization.

Similarly, the proposed regulations for Medicaid and CHIP FFS programs and managed care plans (proposed 42 CFR 431.60(b)(4) and 457.730(b)(4)), require provision of standardized data for clinical data, including laboratory results, through the API, if available, no later than one (1) business day after a claim is adjudicated or the data is received (by the state or the managed care plan/entity). This would ensure that data provided through the API would be the most current data available, which may be critical if the data is being shared by an enrollee with a health care provider who is basing clinical decisions on the data. Like proposed 42 CFR 422.119(c), these Medicaid and CHIP regulations propose compliance with the regulations regarding the USCDI standard, proposed by ONC for HHS adoption at 45 CFR 170.213, as the content and vocabulary standard for the clinical data available through the API; therefore, we are, in

effect, proposing any clinical data included in the USCDI standard, proposed by ONC for HHS adoption at 45 CFR 170.213, be available through the API. For state agencies managing Medicaid or CHIP FFS programs, such data must be included through the API under our proposal only if the state manages clinical data. Our proposed regulation for Medicaid managed care plans at 42 CFR 438.242(b)(6) and CHIP managed care entities at 42 CFR 457.1233(d)(2) would require MCOs, PIHPs, and PAHPs to comply with the same standard in terms of the scope of information and the timing of its availability through the API; the limitation about the availability of clinical data through the API would carry through to managed care plans and entities under our proposal.

Proposed 45 CFR 156.221(b)(3) requires QHP issuers in FFEs to also make available, with the approval of the enrollee, clinical data, including laboratory results, if the QHP maintains such data.

We recognize not all of the entities subject to this requirement have uniform access to this type of data and seek comment on what barriers exist that would discourage them from obtaining, maintaining, and sharing this data. We request comment on these proposals.

(4) Drug Benefit Data, Including Pharmacy Directory, and Formulary Data

We are also proposing that drug benefit data, including pharmacy directory information and formulary or preferred drug list data, also be available through the API at proposed 42 CFR 422.119(b)(2)(ii) and (iii), 431.60(b)(5), and 457.730(b)(5). As previously discussed, Medicaid managed care plans would be required by 42 CFR 438.242(b)(6) to comply with the requirement at 42 CFR 431.60(b)(5), and CHIP managed care entities would be required by 42 CFR 457.1233(d)(2) to comply with the requirement at 42 CFR 457.730(b)(5).

We propose at 42 CFR 422.119(b)(2)(ii) and (iii) that MA organizations offering MA–PD plans make available pharmacy directory data, including the number, mix, and addresses of pharmacies in the plan network, as well as formulary data including covered Part D drugs and any tiered formulary structure or utilization management procedure which pertains to those drugs. The pharmacy directory information is the same information that MA–PD plans—like all Part D plans—must provide on their websites under 42 CFR 423.128(b)(5) and (d)(2). While prescription drug claims would have to be made available through the API no later than 1 business day of the MA–PD plan's receipt of that information, we are not proposing a specific timeframe for pharmacy directory or formulary information to be available (or updated) through the API. We intend that the requirements in 42 CFR part 423 requiring when and how information related to pharmacy directories be updated will apply to the provision of this information through the API; we solicit comment specifically whether we should address this in the regulation text or otherwise impose a time-frame for this information to be made available through the API.

At proposed 42 CFR 431.60(b)(5), for Medicaid FFS programs, and at 42 CFR 457.730(b)(5) for CHIP FFS programs, states would be required to include and update covered outpatient drug lists (including, where applicable, preferred drug lists) through the API no later than one (1) business day after the effective date of the information or any changes. We are proposing to set this timeframe at one (1) business day because we believe that it is critical for beneficiaries and prescribers to have this information as soon as the information is applicable to coverage or in near real time since this information could improve care and health outcomes. Having timely data is particularly important during urgent or emergency situations. Medicaid managed care plans and CHIP managed care entities would be required to comply with these requirements as well under proposed 42 CFR 438.242(b)(6) and 457.1233(d)(2). We also note that adjudicated claims and encounter data referenced in 42 CFR 431.60(b)(1) and (2), 438.242(b)(6), and 457.730(b)(1) and (2) include claims and encounter data for covered outpatient drugs. To the extent that a state or managed care plan utilizes a pharmacy benefit manager (PBM), we anticipate that, as a practical matter, the state or managed care plan would need to obtain the data from the PBM in a timely manner to comply with these proposed requirements.

We request comment on these proposals.

d. Documentation Requirements for APIs

We are proposing that the specific business and technical documentation necessary to interact with the proposed APIs be made freely and publicly accessible. As discussed in section II.A.1 of this proposed rule, we believe transparency about API technology is needed to ensure that any interested third-party application developer can easily obtain the information needed to develop applications technically compatible with the organization's API. Transparency is also needed so that third-parties can understand how to successfully interact with an organization's API, including by satisfying any requirements the organization may establish for verification of developers' identity and their applications' authenticity, consistent with its security risk analysis and related organizational policies and procedures to ensure it maintains an appropriate level of privacy and security protection for data on its systems.

Specifically, at 42 CFR 422.119(d), 431.60(d), 457.730(d), and 45 CFR 156.221(d), we propose virtually identical text to require publication of complete accompanying documentation regarding the API by posting this documentation directly on the applicable entity's website or via a publicly accessible hyperlink. As previously discussed, Medicaid managed care plans would be required by 42 CFR 438.242(b)(6) to comply with the requirement at 42 CFR 431.60(d), and CHIP managed care entities would be required by 42 CFR 457.1233(d)(2) to comply with the requirement at 42 CFR 457.730(d). In requiring that this documentation is ''publicly accessible,'' we expect that any person using commonly available technology to browse the internet could access the information without any preconditions or additional steps beyond downloading and using a third-party application to access data through the API. This is not intended to preclude use of links the user would click to review the full text of lengthy documents or access sources of additional information, such as if the technology's supplier prefers to host technical documentation at a centralized location. Rather, we mean ''additional steps'' to include actions such as: Collecting a fee for access to the documentation; requiring the reader to receive a copy of the material via email; or requiring the user to read promotional material or agree to receive future communications from the organization making the documentation available. We specifically solicit comments on these points.

We propose that the publicly accessible documentation would be required to include, at a minimum, the following information:

- API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.
- The software components and configurations an application must use

in order to successfully interact with the API (for example, to connect and receive data through the API) and process its response(s).

- All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

We note that these information requirements are similar to those ONC has proposed for adoption by HHS for developers and users of health IT certified to the API criteria proposed at 45 CFR 170.315 (published elsewhere in this issue of the **Federal Register**), but are proposed here to apply specifically to the API technology deployed by organizations subject to the API requirements proposed in section III. of this proposed rule. We request comments on this proposal.

e. Routine Testing and Monitoring of Open APIs

At 42 CFR 422.119(c)(2), 431.60(c)(2), 457.730(c)(2), and 45 CFR 156.221(c)(2) for MA organizations, state Medicaid and CHIP FFS programs, and QHP issuers in FFEs, respectively, we are proposing that the API be routinely tested and monitored to ensure it is functioning properly, including assessments to verify that the API is fully and successfully implementing privacy and security features such as but not limited to those minimally required to comply with the HIPAA privacy and security requirements in 45 CFR part 164, 42 CFR parts 2 and 3, and other applicable law protecting privacy and security of individually identifiable health information. Medicaid managed care plans would be required by 42 CFR 438.242(b)(6) to comply with the requirement at 42 CFR 431.60(c), and CHIP managed care entities would be required by 42 CFR 457.1233(d)(2) to comply with the requirement at 42 CFR 457.730(c).

Additionally, we note that while federal laws that regulate MA organizations and MA plans supersede any state law except where noted under section 1856(b)(3) of the Act, some state, local, or tribal laws that pertain to privacy and security of individually identifiable information generally and are not specific to health insurance may also apply to MA organizations and MA plans in the context of our proposal. For the other entities regulated under our proposals in these various programs, we also intend the phrase ''other applicable law'' to include federal, state, tribal or local laws that apply to the entity.

We propose this requirement to establish and maintain processes to routinely test and monitor the open APIs to ensure they are functioning properly, especially with respect to their privacy and security features. Under our proposal, MA organizations, Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs would have to implement, properly maintain, update (as appropriate), and routinely test authentication features that will be used to verify the identity of individual enrollees who seek to access their claims and encounter data and other PHI through the API. Similarly, compliance with our proposed requirements would mean that these entities must implement, maintain, update (as appropriate), and routinely test authorization features to ensure an individual enrollee or their personal representative can only access claims and encounter data or other PHI that belongs to that enrollee. As is the case under existing HIPAA requirements, where an enrollee is also a properly designated personal representative of another enrollee, the HIPAA covered entity must provide for appropriate access to the information of the enrollee that has designated the personal representative, just as they would if the personal representative were an enrollee of the same plan.

Similarly, at proposed 45 CFR 156.221(c)(2), QHP issuers in FFEs would be required to routinely test and monitor their API to confirm that it is functioning properly.

We request comment on these proposals.

f. Compliance With Existing Privacy and Security Requirements

In the hands of a HIPAA covered entity or its business associate, individually identifiable patient claims, encounter data, and other health information are PHI as defined at 45 CFR 160.103. Ensuring the privacy and security of the claims, encounter, and other health information when it is transmitted through the API is of critical importance. Therefore, we remind MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs that mechanisms and practices to release PHI, including but not limited to authorization and authentication protocols and practices must provide protection sufficient to comply with HIPAA privacy and security regulations at 45 CFR part 164 and other law (whether federal, state, tribal or local) that may apply based on the specific circumstances. Under this proposal, the entities subject to these requirements would need to continuously ensure that all authorization and authentication mechanisms provide sufficient protections to enrollee PHI and that they function as intended. We specifically request public comment on whether existing privacy and security standards, including but not limited to those in 45 CFR part 164, are sufficient with respect to these proposals, or whether additional privacy and security standards should be required by CMS as part of this proposal.

g. Issues Related to Denial or Discontinuation of Access to the API

As discussed in section II.A of this proposed rule, HIPAA covered entities must comply with patients' requests to receive their data under the HIPAA Right of Access, including having to transmit patient data to a third party. As noted in guidance from OCR, disagreement with the individual about the worthiness of the third party as a recipient of PHI, or even concerns about what the third party might do with the PHI, are not grounds for denying a request.[27] However, a covered entity is not expected to tolerate unacceptable levels of risk to the PHI held by the covered entity in its systems, as determined by its own risk analysis.[28] Accordingly, it may be appropriate for an organization to deny or terminate specific applications' connection to its API under certain circumstances in which the application poses an unacceptable risk to the PHI on its systems or otherwise violates the terms of use of the API technology.

At 42 CFR 422.119(e), 431.60(e), 438.242(b)(6), 457.730(e), 457.1233(d)(2) and 45 CFR 156.221(e) for MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs, we are proposing to specify the circumstances under which these regulated entities, which are all HIPAA-covered entities subject to HIPAA privacy and security requirements, may decline to establish or may terminate a third-party application's connection to the covered entity's API while remaining in compliance with our proposed requirement to offer patients access through open APIs. We intend for this

[27] *https://www.hhs.gov/hipaa/for-professionals/faq/2037/are-there-any-limits-or-exceptions-to-the-individuals-right/index.html.*

[28] See 45 CFR 164.524(c)(2) and (3), and 164.308(a)(1), OCR HIPAA Guidance/FAQ–2036: *https://www.hhs.gov/hipaa/for-professionals/faq/2036/can-an-individual-through-the-hipaa-right/index.html,* and OCR HIPAA Guidance/FAQ–2037: *https://www.hhs.gov/hipaa/for-professionals/faq/2037/are-there-any-limits-or-exceptions-to-the-individuals-right/index.html* (FAQs last accessed at these URLs July 30, 2018).

proposal to be consistent with the HIPAA rules, and we note that these circumstances apply to specific applications, rather than the third party itself. For instance, were the individual to request that the HIPAA covered entity provide the individual's information through other means than through an API to the same third party that would have received it on the individual's behalf through an application which has been denied access, the covered entity would be required to approach that request as if the application's API request or connection had not occurred.

Specifically, we propose that an MA organization, state Medicaid and CHIP FFS program, Medicaid managed care plan, CHIP managed care entity, or QHP issuer in an FFE, may, in accordance with HIPAA, deny access to the API if the entity reasonably determines that allowing that application to connect or remain connected to the API would present an unacceptable level of risk to the security of PHI on the organization's systems. We further propose that this determination must be based on objective, verifiable criteria that are applied fairly and consistently across all applications through which enrollees seek to access their electronic health information as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

Where we propose to require access through open APIs to otherwise publicly available information, such as provider directories, the entities subject to our proposal may also deny or terminate an application's connection to the API when it makes a similar determination about risk to its systems. However, depending on how the organization's systems are designed and configured, we recognize that the criteria and tolerable risk levels appropriate to assessing an application for connection to an API for access to publicly available information may differ from those required for API access to non-published PII.

We also anticipate that, where an application's connection has been terminated under these circumstances, it might be feasible in some instances for the organization to allow the application to re-connect to the API if and when the flaw or compromise of the application has been addressed sufficiently that the organization can no longer fairly say the application's API connection continues to pose an unacceptable risk.

We request comment on these proposals.

h. Enrollee and Beneficiary Resources Regarding Privacy and Security

As discussed in section II.A. of this proposed rule, we are committed to maximizing enrollees' access to and control over their health information. We believe this calls for providing enrollees that would access data under our proposal with essential information about the privacy and security of their information, and what to do if they believe they have been misled or deceived about an application's terms of use or privacy policy.

At 42 CFR 422.119(g), 431.60(f), and 457.730(f), and 45 CFR 156.221(g), we propose to require MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs, to make available to their current and former enrollees certain information about: Factors to consider in selecting a health information management application, practical strategies to help them safeguard the privacy and security of their data, and how to submit complaints to OCR or FTC. These proposed obligations are proposed to apply to Medicaid managed care plans and CHIP managed care entities through cross-references proposed in 42 CFR 438.242(b)(6) and 457.1233(d)(2).

The general information about the steps individuals can take to help protect the privacy and security of their health information should not be limited to, but should specifically include and emphasize the importance of understanding the privacy and security practices of any application to which they entrust their data. Information about submitting complaints should include both specific contact information for the OCR and FTC complaints processes and a brief overview, in simple and easy-to-understand language, of: What organizations are HIPAA covered entities, OCR's responsibility to oversee compliance with HIPAA, and FTC's complementary responsibility to oversee unfair and deceptive practices, including by non-covered entities that may offer direct-to-consumer health information management applications.

We propose that this information must be made available on the website of the organization subject to this proposed requirement, and through other appropriate mechanisms through which the organization ordinarily communicates with enrollees. This could include customer portals, online customer service help desks, and other locations, such as any portals through which enrollees and former enrollees might request disclosure of their data to a third-party application through the organization's API. We are also proposing that the entity must make this information available in non-technical, consumer-friendly language.

We anticipate that organizations could meet the requirement to provide information to current and former enrollees in whole or in part using materials designed for consumer audiences that are available on the HHS website (for example, content and materials such as those available at *https://www.hhs.gov/hipaa/for-individuals/right-to-access/index.html*) and FTC website (for example, content and materials such as those available at *https://www.consumer.ftc.gov/topics/online-security*). However, we note that whether the organization chooses to draft its own resource materials to provide the required information or to rely on governmental or other sources for such materials, the organization will be responsible for ensuring that the content of the materials remains current as relevant law and policy may evolve over time. We seek comment on this proposal, and we invite additional comments on what specific information resources in addition to those already available on the websites noted above would be most useful to entities in meeting this requirement. We anticipate using this feedback to help inform HHS planning and prioritization of informational resource development work in addition to making a decision on the final rule regarding this proposal.

i. Exceptions or Provisions Specific to Certain Programs or Sub-Programs

We are proposing certain exceptions or specific additional provisions as part of this proposed rule for certain QHPs in FFEs and certain types of MA plans, respectively. Under sections 1856, 1857, and 1860D–12(b)(3) of the Act, we proposed at 42 CFR 422.119(b)(2) to include additional requirements that would apply specifically to MA organizations that offer Medicare Advantage-Prescription Drug (MA–PD) plans. The organizations offering these MA–PD plans must comply with MA requirements in 42 CFR part 422 for Part A, Part B and non-drug supplemental benefits; they must comply with Part D requirements in 42 CFR part 423 for the Part D prescription drug benefit. These additional requirements would ensure that enrollees of MA–PD plans can easily access the information they need in order to adhere to their care plans. Including this information in an open API allows non- MA third-party applications to properly use, aggregate, and display plan data in different

contexts, enabling another means of accessing information for patients and more options for comparing and understanding plan information in a way that can best serve their individual needs.

Specifically, at 42 CFR 422.119 (b)(2)(i), we propose to require MA organizations make standardized data concerning adjudicated Part D claims, including remittances and enrollee cost-sharing, available through the API to enrollees covered under a MA–PD plan. We propose to require that this information be made available no later than one (1) business day after a claim is adjudicated. This would ensure that data provided through the API would be the most current data available, which may be critical if the data is being used by a provider who is basing clinical decisions on the data. To the extent that an MA organization offering MA–PD plans utilizes a PBM, the MA organization would be required to obtain the data from the PBM in order to comply with these requirements.

Related to QHP issuers, we propose two exceptions to this proposed rule. First, we propose that the requirements proposed in 45 CFR 156.221(a) not apply to issuers of SADPs in the FFEs. In contrast to QHP issuers of medical plans, issuers of SADPs offer enrollees access to a unique and specialized form of medical care. We believe the proposed standards and health IT investment would be overly burdensome for SADP issuers as related to their current enrollment and premium intake and could result in SADP issuers no longer participating in FFEs, which would not be in the best interest of enrollees. Additionally, we believe much of the benefit to enrollees from requiring issuers of QHPs to make patient data more easily available through a standard format depends upon deployment of open API technology that conforms to standards proposed by ONC for HHS adoption at 45 CFR 170.215 (published elsewhere in this issue of the **Federal Register**) and a corresponding energetic response by the developer community in developing innovative, useful, usable, and affordable consumer-facing applications through which plan enrollees can conveniently access, use, and share their information as they choose. Through our proposals in this section to require implementation of open API technology in the Medicare, Medicaid and CHIP programs, as well as by QHP issuers in FFEs, we would anticipate significantly expanding the implementation of open APIs by medical plans. However, we do not anticipate similar widespread usage with respect to SADPs. Therefore, we believe that the utility of access to issuers' data is less applicable to dental coverage, and do not believe it would be in the interest of qualified individuals and qualified employers in the state in which an FFE operates to *not* certify SADPs because they do not provide patient access to their data through an openly-published API. We seek comment on whether we should apply this policy to SADP issuers in the future.

We also propose to provide an exceptions process through which an FFE may certify health plans that do not provide patient access through an openly-published API, but otherwise meet the requirements for QHP certification. We propose in 45 CFR 156.221(h)(1) that if a plan applying for QHP certification to be offered through an FFE does not provide patient access to their data through an open API, the issuer must include as part of its QHP application a narrative justification outlining the reasons why the plan cannot reasonably satisfy the requirements in proposed 45 CFR 156.221(a),(b), or (c), the impact of non-compliance upon enrollees, the current or proposed means of providing health information to enrollees, and proposed solutions and timeline to achieve API compliance. In 45 CFR 156.221(h)(2), we propose that an FFE may grant an exception to the requirement to provide enrollees access to data through open API technology if the FFE determines that making available such health plan is in the interest of qualified individuals and qualified employers in the state in which the FFE operates. We anticipate that this exception would be provided in limited situations. For example, we would consider providing an exception for small issuers, issuers who are only in the individual or small group market, financially vulnerable issuers, or new entrants to the market who demonstrate that deploying open API technology consistent with the required interoperability standards would pose a significant barrier to the issuer's ability to provide coverage to consumers, and not certifying the issuer's QHP or QHPs would result in consumers having few or no plan options in certain areas. We seek comment on other circumstances in which the FFE should consider providing an exception.

j. Applicability and Timing

At 42 CFR 422.119(h) and 45 CFR 156.221(i), we are proposing specific provisions regarding applicability and timing for MA organizations and QHP issuers in FFEs that would be subject to our proposal. We are not proposing specific regulation text for 42 CFR 431.60 or 438.242 because we intend to make the regulation text effective on the applicable date discussed below. We expect that state Medicaid and CHIP agencies will be aware of upcoming new regulations and planning for compliance with them when they are effective and applicable, even if the new regulation is not yet codified in the CFR; we similarly expect that such agencies will ensure that their managed care plans/entities will be prepared for compliance. Unlike Medicaid state agencies and managed care plans and state CHIP agencies and managed care entities, MA organizations and QHP issuers in FFEs generally are subject to rules regarding bid and application submissions to CMS in advance of the coverage period; for example, MA organizations must submit bids to CMS by the first Monday in June of the year before coverage starts in order to be awarded an MA contract. In order to ensure that these requirements for MA organizations and QHP issuers in FFEs are enforceable and reflected in the bids and applications these entities submit to us in advance of when the actual requirements must be met, we propose to codify the actual compliance and applicability dates of these requirements. We solicit comment on this approach.

For MA organizations, under 42 CFR 422.119(h), we are proposing that the requirements would be effective beginning January 1, 2020. Under this proposal, the requirements we propose for 42 CFR 422.119 would be applicable for all MA organizations with contracts to offer any MA plan on that date and thereafter. We request feedback about this proposed timing from the industry. In particular, we are interested in information and request comment from MA organizations about their current capability to implement an API consistent with this proposal and the costs associated with compliance by January 1, 2020, versus compliance by a future date.

For Medicaid FFS at 42 CFR 431.60, CHIP agencies that operate FFS systems at 42 CFR 457.730, Medicaid managed care plans at 42 CFR 438.242(b)(6), and CHIP managed care entities at 42 CFR 457.1233(d)(2), we are proposing that the API requirements would be effective beginning July 1, 2020, regardless of when the managed care contract started. Given the expected date of publication of this proposed rule and potential final rule, we believe July 1, 2020, would provide state Medicaid agencies and CHIP agencies that operate FFS systems, Medicaid managed care plans, and CHIP managed care entities sufficient time to implement. We solicit comment on this

proposal and whether additional flexibility would be necessary to take into account the contract terms that states use for their Medicaid managed care plans.

For CHIP, we are aware that some states do not provide any benefits on a FFS basis, and we do not intend for those states to implement an API outside their managed care plans. Therefore, we also propose in 42 CFR 457.700(c) that separate CHIP agencies that provide benefits exclusively through managed care entities may meet the requirements of 42 CFR 457.730 by requiring the managed care entities to meet the requirements of 42 CFR 457.1233(d)(2) beginning July 1, 2020.

For QHP issuers in FFEs, we propose in 45 CFR 156.221(i) that these requirements would be applicable for plan years beginning on or after January 1, 2020. We seek comment on the timing of these requirements, and on how long issuers, particularly smaller issuers, anticipate it would take to come into compliance with these requirements.

We believe that these proposals would help to create a health care information ecosystem that allows and encourages the health care market to tailor products and services to compete for patients, thereby increasing quality, decreasing costs, and helping them live better, healthier lives. Additionally, under these proposals, physicians would be able to access information on their patient's current prescriptions and services by reviewing the information with the patient on the patient's personal device or by the patient sharing data with the provider's EHR system, which would save time during appointments and ultimately improve the quality of care delivered to beneficiaries. Most health care professionals and consumers have widespread access to the internet, providing many access points for viewing health care data over secure connections. We believe that these proposed requirements would significantly improve beneficiaries' experiences by providing a secure mechanism through which they can access their data in a standardized, computable format.

These proposals are designed to empower patients by making sure that they have access to health information about themselves in a usable digital format and can make decisions about how, with whom, and for what uses they will share it. By making claims data readily available and portable to the enrollee, these initiatives support efforts to move our health care system away from a FFS payment system that pays for volume and toward a payment system that pays for value and quality by reducing duplication of services, adding efficiency to patient visits to providers; and, facilitating identification of fraud, waste, and abuse. Data interoperability is critical to the success of new payment models and approaches that incentivize high quality, efficient care. All of the health care providers for a patient need to coordinate their care for a value-based system to work, and that requires information to be securely shareable in standardized, computable formats. Moreover, patients need to understand and be actively involved in their care under a value-based framework. We are committed to supporting requirements that focus on these goals, and we believe that these specific proposals in this proposed rule support these efforts.

k. Request for Information on Information Sharing Between Payers and Providers Through APIs

This proposed rule requires the implementation of open APIs for making accessible data that a third-party could use to create applications for patients to access data in order to coordinate and better participate in their medical treatment. While in some instances, direct provider to health plan transmission of health information may be more appropriate than sharing data through an open API, in other instances a patient may wish to send a provider a copy of their health information via another health care provider's API. In such cases, patients could direct the payer to transmit the health information to a third party application (for example, an application offered by a health care provider to obtain patient claims and encounter data, as well as lab test results (if applicable) on a one-off and as-needed basis. To the extent a HIPAA covered entity uses a third party application to offer patients access to their records, another HIPAA covered entity may be able to obtain an individual's health information from the app for treatment, payment, or certain health care operations, if it could do so in accordance with HIPAA without need of an individual's authorization. (*See* 45 CFR 164.506.) Under other laws, providers may need to obtain specific individual consent to obtain health information related to care provided by a behavioral health provider, treatment received at a substance use disorder treatment facility, certain 42 CFR part 2-covered diagnoses or other claims-related information, or labs that suggest a part 2 diagnosis. We do not intend to expand any scope of authority to access patient data nor to contravene existing requirements related to disclosure of PHI under the HIPAA Rules and other legal standards, but instead specify a new and additional mechanism by which to share health information as directed by the individual, through the use of API technology in compliance with all existing federal, state, local, and tribal privacy and security laws.

In the future, we anticipate payers and providers may seek to coordinate care and share information in such a way as to request data on providers' or a plan's patient/insured overlapping population(s) in one transaction. Effective care coordination between plans and providers can inform health care providers about where their patients are receiving care to better understand the totality of their healthcare needs and manage their care. We have heard that being aware of urgent care or emergency department visits allows clinicians to arrange appropriate follow-up, modify treatments, and update records if services are provided (for example, tetanus boosters given with a laceration treated in urgent care). The accompanying proposals in Section X. of this proposed rule, to amend the conditions of participation regarding notification of patient discharge, further support the ability of clinicians to arrange and affirm such appropriate follow-up care. Having a complete record of tests done at specialists' offices can reduce duplicate testing. Having a complete list of clinicians caring for a patient facilitates appropriate notification if treatments are changed or procedures are planned that may impact the other clinicians' treatment plan. We have heard from participants in our accountable care programs and models that organizations taking risk for their patient populations need to have a complete picture of the patients' needs to better budget for appropriate resources. This may be particularly relevant during disasters or public health emergencies when patients are not able to access their normal sources of care and/or health care facilities are overwhelmed due to patient surge.

We believe there are a variety of transmission solutions that may be employed to share data regarding a provider's and plan's overlapping patient populations. For instance, some geographic areas might have regional health information exchanges that could coordinate such transmissions. Elsewhere, direct provider-to-provider and plan-to-plan exchange might be more appropriate. Plans could participate in direct exchange through existing trusted networks, or beneficiary-facing third party

applications could meet this potential future requirement.

We seek comment for possible consideration in future rulemaking on the feasibility of providers being able to request a download on a shared patient population, and whether such a process could leverage the APIs described in sections II.A.3. and III.C. of this proposed rule. We seek comment on requirements for patient notice and consent, and applicable legal and regulatory requirements, and whether or how this data transfer could be cumulative over time and between various providers. We seek input on the utility to providers of obtaining all of their patients' utilization history in a timely and comprehensive fashion. We also seek input on potential unintended consequences that could result from allowing a provider to access or download information about a shared patient population from payers through an open API. Finally, we seek comment on the associated burden on plans to exchange this data, as well as the identification other potential statutory or regulatory barriers to exchanging this data.

IV. API Access to Published Provider Directory Data

A. Interoperability Background and Use Cases

The proposals described in section III of this proposed rule primarily focus on patient access to their data through a standardized, transparent API; however, we have also proposed that entities subject to these proposals make available certain plan-level data through the API. In this section, we provide additional context for the proposal related to making provider directory information available through the API, including ways in which this proposal may differ from our other proposals related to accessibility of patient data.

Provider directories make key information about health care professionals and organizations available to help consumers identify a provider when they enroll in an insurance plan or as new health needs arise. For example, such information might include hours of operation, languages spoken, specialty/services, availability for new patients. Provider directories also function as a resource used by the provider community to discover contact information of other providers to facilitate referrals, transitions of care, and care coordination for enrollees.

The current applicable regulations for MA plans (42 CFR 422.111) and Medicaid and CHIP managed care plans (42 CFR 438.10(e)(2)(vi) and (h) and 457.1207, respectively) require that provider directories be made available to enrollees and potential enrollees in hard copy and on the plan's website. Section 1902(a)(83) of the Act requires state Medicaid agencies to publish a directory of certain physicians on the public website of the State agency. A regulation for QHPs in FFEs (45 CFR 156.230(b)) requires public access to the QHP's provider directory in addition to distribution and access for enrollees. In addition to directing that this information be accessible, the current regulations also address the content of such directories and the format and manner in which MA plans, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs make the information available.

Making this required provider directory information available to enrollees and prospective enrollees through an API could support development of applications (whether standalone or integrated with providers' EHR technology) that would pull in current information about available providers to meet enrollees' current needs. For instance, as part of a referral lookup use case, API access to a provider directory could allow for a referring provider's health IT to enable either the enrollee or the provider to easily identify up-to-date contact information obtained from the directory through an API, and securely send the receiving health care provider the patient information needed to provide safe, high-quality care sensitive to the patient's preferences. Broad availability of provider directory data through interoperable API technology would also allow for innovation in applications or other services that help enrollees and prospective enrollees to more easily compare provider networks while they are considering their options for changing health plans. Finally, a consistent, FHIR-based API-driven approach to making provider directory data accessible could reduce provider burden by enabling payers/plans to share more widely basic information about the providers in their networks, such as provider type, specialty, contact information, and whether or not they are accepting new patients.

B. Broad API Access to Provider Directory Data

In sections II.A.3. and III.C. of this proposed rule, we propose to require MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to make standardized information about their provider networks available through API technology, so that third party software could access and publish that information. Such availability would be for current enrollees, prospective enrollees and possibly the general public to the extent existing regulations require that information to be disclosed beyond current enrollees. We propose to require that the API technology conform to the API standards proposed by ONC for HHS adoption at 45 CFR 170.215 (published elsewhere in this issue of the **Federal Register**). At this time, because QHP issuers in FFEs are already required to make provider directory information available in a specified, machine-readable format,[29] we do not propose these as requirements for QHP issuers. However, we seek comment as to whether this same requirement should apply to QHP issuers, or if such a requirement would be overly burdensome for them.

We note that, since the provider directory information we are proposing to require be available through the API is already available and accessible to enrollees without cost to them, this information should be as accessible through the API as it is required to be when posted on the organization's websites. Therefore, the security protocols proposed at 45 CFR 170.215 that are specific to authenticating users and confirming individuals' authorization or request to disclose their personal information to a specific application would not apply to public access to provider directory information through APIs. While we are aware the organization will nevertheless need to take appropriate steps to mitigate the potential security risks of allowing any application to connect to the API through which it offers provider directory access, we emphasize that these steps should be appropriate to the level of risk associated with the specific use case of accessing otherwise public information through API technology. Those wishing to access this data should not be unduly burdened by security protocols that are not necessary to provide the appropriate degree of protection for the organization's systems and data.

As referenced in sections II. and III. of this proposed rule, we intend to develop additional guidance, incorporating feedback from industry that provides implementation best practices relevant to FHIR-conformant open APIs to help organizations subject to the requirements proposed in this rulemaking. To that end, we solicit

[29] Available at *https://github.com/CMSgov/QHP-provider-formulary-APIs/blob/master/README.md.*

comment on what specific resources would be most helpful to organizations implementing APIs under requirements proposed in this proposed rule.

V. Health Information Exchange and Care Coordination Across Payers: Establishing a Coordination of Care Transaction To Communicate Between Plans

We are proposing a new requirement for Medicare Advantage (MA) plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs to require these plans to maintain a process to coordinate care between plans by exchanging, at a minimum, the USCDI at enrollee request at the specific times specified in the proposed regulation text. Understanding that this information could already be available for exchange between plans, this proposal is specifically requiring this information sharing not only occur when initiated by an enrollee request, but that the information requested, in the form of the USCDI data set, would then be incorporated into the recipient plan's systems. The USCDI (Version 1) data set would have to be sent to another plan that covers the enrollee or a recipient identified by the enrollee at any time during coverage or up to 5 years after coverage ends, and the plan would have to receive the USCDI (version 1) data set from any health plan that covered the enrollee within the preceding 5 years. Under our proposal we are supporting patient directed coordination of care and each of the plans subject to the requirement would, upon an enrollee's request: (1) Accept the data set from another plan that had covered the enrollee within the previous 5 years; (2) send the data set at any time during an enrollee's enrollment and up to 5 years later, to another plan that currently covers the enrollee; and (3) send the data set at any time during enrollment or up to 5 years after enrollment has ended to a recipient identified by the enrollee.

As we discussed in section III.C.2. of this proposed rule, this proposal is based on our authority under sections 1856(b) and 1857(e) of the Act to adopt standards and contract terms for MA plans; section 1902(a)(4) of the Act to adopt methods of administration for state Medicaid plans, including requirements for Medicaid managed care plans (MCOs, PIHPs, and PAHPs); section 2101(a) of the Act for CHIP managed care entities (MCOs, PIHPs, and PAHPs); and section 1311(e)(1)(B) of the ACA for QHP issuers in an FFE (not including SADP issuers). We believe that our proposal will help to reduce provider burden and improve patient access to their health information through coordination of care between health plans. We also note that the CHIP regulations incorporate and apply, through an existing cross-reference at 42 CFR 457.1216, the Medicaid managed care plan requirements codified at 42 CFR 438.62(b)(1)(vi). Therefore, the proposal for Medicaid managed care plans described above will also apply to CHIP managed care entities without new regulation text in part 457. We are proposing that this new requirement would be effective starting January 1, 2020 for MA plans, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs. Among other topics related to this proposal, we solicit comments on this proposed effective date.

We propose to codify this new requirement at 42 CFR 422.119(f)(1) for MA organizations; at 42 CFR 438.62(b)(1)(vi) for Medicaid managed care plans (and by extension under existing rules in part 457, to CHIP managed care entities); and at 45 CFR 156.221(c) for QHPs in FFEs. This proposed new requirement is virtually identical for MA plans, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs, with modifications in the proposal necessary for specific plans types to account for the program needs of the MA program, Medicaid and CHIP managed care programs, and QHP program. Our proposed regulation text references the content standard adopted at 45 CFR 170.213, which ONC is proposing as the USCDI Version 1 data set (published elsewhere in this issue of the **Federal Register**). We believe that exchanging this minimum data would help both plan enrollees and health care providers coordinate care and reduce administrative burden to ensure that plans provide coordinated high-quality care in an efficient and cost-effective way that protects program integrity.

Leveraging interoperability to facilitate care coordination among plans can, with thoughtful execution, significantly reduce unnecessary care, as well as ensure that health care providers are able to spend their time providing care rather than performing unnecessary administrative tasks. We believe that use of the USCDI to exchange information furthers care coordination. For instance, effective information exchange between plans could improve care coordination by reducing the need for health care providers to write unneeded letters of medical necessity; by reducing instances of inappropriate step therapy; and by reducing repeated utilization reviews, risk screenings, and assessments. It can also streamline prior authorization processes and reduce instances where an enrollee's health care provider needs to intervene personally with the enrollee's MA plan, Medicaid managed care plan, CHIP managed care entity, or QHP in the FFE to ensure his or her patient received the necessary treatment. This addresses concerns stakeholders have previously raised with CMS and ONC regarding such administrative burdens, as the USCDI standard contains many of the data points required to more effectively coordinate care.

In addition to the benefits for care coordination at the plan level and reduced provider burden, we note that once the combined health information, specified by the USCDI standard, from a prior plan is available to the patient's current plan, the enrollee would also have access to multiple years of their health information through the proposed patient access API discussed in section III of this proposed rule. The USCDI (Version 1) data set includes laboratory results and tests, medications, health concerns, assessment and plan of treatment, care teams, clinical notes, and other data points essential for care coordination. This would provide the patient with a more comprehensive history of their medical care, helping them to make better informed health care decisions. We seek comments on how plans might combine records and address error reconciliation or other factors in establishing a more longitudinal record for each patient.

We propose to allow multiple methods for electronic exchange of the information, including use of the APIs proposed in section III. of this proposed rule, to allow for patient-mediated exchange of payer information or direct payer-to-payer communication, subject to HIPAA requirements, 42 CFR part 2, and other applicable laws. We considered requiring the use of the FHIR-based API discussed in section III. of this proposed rule for the information exchange; however, we understand that some geographic areas might have a regional health information exchange that could coordinate such transitions for the MA plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs that are subject to this proposal. We seek comment on whether it would be beneficial to interoperability and patient care coordination for us to require the use of the FHIR-based API discussed in section III. of this proposed rule, and whether this should be the only mechanism allowed for this exchange, or whether

multiple methods for electronic exchange of the information should be allowed under this proposed policy.

We also propose that a patient should be able to request his or her information from their prior plan up to 5 years after dis-enrollment, which is considerably less than existing data retention policies for some of the plans.[30] Further, if a plan has access to multiple years of health information for a patient, either due to the fact that the patient has been enrolled with the plan for multiple years, or because the enrollee has requested transfer of the health information from prior plans which previously covered the enrollee, we propose that the health information would be incorporated into the IT and data systems of each plan that receives the USCDI data set under this proposed requirement, such that the enrollee's data would be cumulative and move with the enrollee as he or she changes enrollment. For example, if a patient is enrolled in Plan 1 in 2020 and Plan 2 in 2021, then requests the data from Plan 1 to be sent to Plan 2, Plan 2 would have at least 2 years (2020 and 2021) of health information for that patient. If the patient moves to Plan 3 in 2022, Plan 3 should receive both 2020 and 2021 data from Plan 2 at the patient's request. While our proposal is to require compliance (and thus exchange of these data sets) only by MA plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs, we hope that compliance by these plans could be the first step toward adoption and implementation of these standards on a voluntary basis by other health plans and health issuers throughout the health care system.

Research indicates that the completeness of a patient record and the availability of up-to-date and relevant health information at the point of care can have a significant impact on patient outcomes.[31] Our proposal here for MA plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs to exchange a minimum data set in particular scenarios would support improvement in care coordination by allowing for sharing of key patient health information when an enrollee requests it. The USCDI (Version 1) data set would have to be sent to another plan that covers the enrollee or a recipient identified by the enrollee at any time during coverage or up to 5 years after coverage ends and the plan would have to receive the USCDI (version 1) data set from any health plan that covered the enrollee within the preceding 5 years.

We propose that the plans subject to this new requirement would be required to exchange, at a minimum, the USCDI Version 1 data set. On behalf of HHS, ONC has proposed to adopt the USCDI as a standard (published elsewhere in this issue of the **Federal Register**), to be codified at 45 CFR 170.213, and our proposed regulation text cross-references this regulation. These data exchanges would provide the enrollee's new plan with a core set of data that can be used to support better care coordination and improved outcomes for the enrollee. We considered requiring plans to exchange all the data that we proposed be available through an API (see section III. of this proposed rule) but we understand that ingesting data and reconciling errors has challenges and proposed this more limited data set to address those concerns. We are seeking comment on whether the USCDI data set is comprehensive enough to facilitate the type of care coordination and patient access described in this proposal, or whether additional data fields and data elements that would be available under our API proposal in section III of this proposed rule, should also be required.

Many key attributes of the USCDI make it suitable for the purpose outlined in our proposal. The USCDI includes data classes that can be supported by commonly used standards, including the Health Level Seven (HL7®) Consolidated Clinical Data Architecture (C–CDA) Version 2.1 and the Fast Healthcare Interoperability Resources (FHIR®) standards for essential patient health information like vital signs, lab results, medications and medication allergies. The USCDI establishes a minimum set of data elements that would be required to be interoperable nationwide and is designed to be expanded in an iterative and predictable way over time. The USCDI, at a minimum, transferred for each enrollee moving among the plans subject to our proposal would greatly improve each plan's coordination of care efforts and spotlight areas of urgent need. Having this information would allow the new MA plan, Medicaid managed care plan, CHIP managed care entity or a QHP in the FFE to evaluate and review an enrollee's utilization history in a timely and comprehensive fashion and thus assist each enrollee to transition to the new plan with minimal disruption to care. By being able to perform timely outreach to enrollees based on past and current utilization, these plans could take steps to prevent unnecessary emergency room visits and lapses in medication and ongoing care; further, they could proactively address any network deficiencies that may impact the enrollee. We believe that having an enrollee's utilization history in a timely and comprehensive fashion would facilitate outreach and coordination efforts in ways heretofore unavailable on a broad basis. In all, this ability would mean that these plans could help new enrollees transition to new coverage rules and a new network with minimal disruptions to care.

While our proposal is to require, at a minimum, exchange of the USCDI Version 1 data set, we reiterate that we do not propose to specify the means of exchanging this data at this time. While we anticipate that plans may opt to use APIs (such as those described in section III of this proposed rule) as the means to exchange this data, we intend to not be overly prescriptive as to how USCDI data set information for applicable enrollees is exchanged as we expect there are a variety of transmission solutions that may be employed. For instance, some geographic areas might have a regional health information exchange that could coordinate such transitions for the MA plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs that are subject to this proposal. Elsewhere, direct plan-to-plan exchange might be more appropriate, or beneficiary-facing third party applications could be used by MA plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs to meet this proposed requirement. We also expect there may be instances where these plans may leverage their connections to Health Information Exchanges to engage in the information exchanges necessary to comply with this proposed rule. We expect enrolled beneficiaries to have constant access to requesting an exchange of data as our proposal would require exchange of the USCDI data set whenever an enrollee makes such a request, which may occur at times other than enrollment or disenrollment. We request comments on other means that the applicable plans may prefer to use for meeting this requirement and whether CMS might be able to leverage its program authority to facilitate the data exchanges contemplated by this proposal. We acknowledge that in some cases plans subject to this proposed requirement may be exchanging patient health information with other plans that are not similarly required to exchange

[30] Under 42 CFR 422.504(d) and 438.3(u), MA organizations and Medicaid managed care plans and CHIP plans must retain records for at least 10 years. Under 45 CFR 156.705; 45 CFR 155.1210(b)(2), (3) and (5) QHPs in the FFEs must also retain records for 10 years.

[31] *https://www.healthit.gov/topic/health-it-basics/improved-diagnostics-patient-outcomes.*

USCDI data sets for enrollees, and we request comment on how to support patients and providers in those situations.

We believe that this proposed requirement would also support dual eligible individuals who are concurrently enrolled in MA plans and Medicaid managed care plans. Under our proposal, both of the dual eligible individual's plans would be subject to the requirement to exchange that individual's data in the USCDI Version 1, which should improve the ability of both plans to coordinate care based on that data. For example, when an enrollee is initially eligible for only one program (that is, only for Medicare and enrolled in a MA plan, or only for Medicaid and enrolled in a Medicaid MCO) and then becomes dually eligible for a second program, the sharing of data between the existing plan and the new plan reduces the burden on the new plan, on the enrollee, and on health care providers in the new plan regarding collecting information about prior utilization or health information. Rather than completing a lengthy health assessment, the enrollee in this example would benefit from having similar (or possibly the same) information transferred directly between the MA plan and the Medicaid managed care plan under our proposal. We seek comment on how plans should coordinate care and exchange information in those situations. We also seek comment on the associated burden on plans to exchange the USCDI data set under our proposal. In addition, we are interested in comments about potential legal barriers to exchanging the USCDI data set as would be required under our proposal; for example, are there federal, state, local and tribal laws governing privacy for specific use cases (such as in the care of minors or for certain behavioral health treatments) that raise additional considerations we should address in this regulation or guidance.

We believe that activities related to this proposal may qualify as a quality improvement activity (QIA) meeting the criteria described in section 2718(a)(2) of the PHSA for purposes of the Medical Loss Ratio (MLR) requirements for QHP issuers in an FFE (excluding SADP issuers),[32] and similar standards for treatment of quality improvement standards applicable to Medicaid managed care plans (MCOs, PIHPs, and PAHPs) under 42 CFR 438.8, CHIP managed care entities under 42 CFR 457.1203(f), and MA plans under 42 CFR 422.2400 through 422.2490. We request comments related to this assumption and its implications.

VI. Care Coordination Through Trusted Exchange Networks: Trust Exchange Network Requirements for MA Plans, Medicaid Managed Care Plans, CHIP Managed Care Entities, and QHPs in the FFEs

We are proposing to require MA plans, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs (excluding SADP issuers) to participate in trust networks in order to improve interoperability in these programs. We would codify this requirement in, respectively, 42 CFR 422.119(f)(2), 438.242(b)(5), and 457.1233(d) (which cross-references the requirements in 42 CFR 438.242(b)(5)) and 45 CFR 156.221. In general, payers and patients' ability to communicate between themselves and with health care providers could considerably improve patient access to data, reduce provider burden, and reduce redundant and unnecessary procedures. Trusted exchange networks allow for broader interoperability beyond one health system or point to point connections among payers, patients, and providers. Such networks establish rules of the road for interoperability, and with maturing technology, such networks are scaling interoperability and gathering momentum with participants, including several federal agencies, EHR vendors, retail pharmacy chains, large provider associations, and others.

The importance of a trusted exchange framework to such interoperability is reflected in section 4003(b) of the Cures Act, as discussed in more detail in section I.D. of this proposed rule. A trusted exchange framework allows for the secure exchange of electronic health information with, and use of electronic health information from, other health IT without special effort on the part of the user. Widespread payer participation in such a framework might allow for more complete access and exchange of all electronically accessible health information for authorized use under applicable state or federal law, which we believe would lead to better use of such data. While we cannot require widespread payer participation in trust networks, we are proposing here to use our program authority in the MA program, Medicaid managed care program, CHIP managed care program, and QHP certification program for the FFEs to increase participation in trust networks and to bring the benefits of such participation to those programs.

We are proposing to require, effective beginning January 1, 2020, that MA plans, Medicaid managed care plans, CHIP managed care entities and QHPs in the FFEs (excluding not stand alone SADPs) participate in a trusted exchange network. This proposal is based on our authority under: Sections 1856(b) and 1857(e) of the Act to adopt standards and contract terms for MA plans; section 1902(a)(4) of the Act to adopt methods of administration for the administration state Medicaid plans, including requirements for Medicaid Managed Care Plans (MCOs, PIHPs, and PAHPs); section 2101(a) for CHIP managed care entities (MCOs, PIHPs, and PAHPS); and section 3001(c)(9)(F)(iii) of the Public Health Service Act and section 1311(e)(1)(B) of the Affordable Care Act for QHP issuers in an FFE. Under our proposal, participation would be required in a trusted exchange framework that meets the following criteria:

(1) The trusted exchange network must be able to exchange PHI, defined in 45 CFR 160.103, in compliance with all applicable state and federal laws across jurisdictions.

(2) The trusted exchange network must be capable of connecting both inpatient EHRs and ambulatory EHRs.

(3) The trusted exchange network must support secure messaging or electronic querying by and between patients, providers and payers.

We propose to codify these requirements for these plans at 42 CFR 422.119(f)(2) for MA organizations, 438.242(b)(5) for Medicaid managed care plans, 457.1233(d)(2) for CHIP managed care entities, and 45 CFR 156.221(d) for QHPs in the FFEs.

On January 5, 2018, ONC released the draft Trusted Exchange Framework for public comment. Commenters to the draft framework, particularly payers providing comments, requested that existing trust networks operating successfully be leveraged in further advancing interoperability; thus, we are considering proposing in the future an approach to payer to payer and payer to provider interoperability that leverages existing trust networks to support care coordination and improve patient access to their data. We request comments on this approach and how it might be aligned in the future with section 4003(b) of the Cures Act. We also request comments on the effective date we have proposed for this requirement and what benefits and challenges the plans (MA organization, Medicare managed care plans, CHIP managed care entities and QHPs in the FFE) may face meeting this requirement for additional consideration in future rulemaking.

[32] While this rulemaking is specific to QHP issuers participating in FFEs, we note that to the extent other commercial market issuers incur similar costs for coverage sold in the individual or group markets, those expenses may similarly qualify as QIA.

We believe that activities related to this proposal may qualify as a QIA meeting the criteria described in section 2718(a)(2) of the PHSA for purposes of the MLR requirements for QHP issuers in an FFE (excluding SADP issuers),[33] and similar standards for treatment of quality improvement standards applicable to Medicaid managed care plans (MCOs, PIHPs, and PAHPs) under 42 CFR 438.8, CHIP managed care entities under 42 CFR 457.1203(f), and MA plans under 42 CFR 422.2400 through 422.2490. We request comments related to this assumption and its implications.

VII. Improving the Medicare-Medicaid Dually Eligible Experience by Increasing the Frequency of Federal-State Data Exchanges

A. Increasing the Frequency of Federal-State Data Exchanges for Dually Eligible Individuals

1. Background

The Medicare and Medicaid programs were originally created as distinct programs with different purposes. The programs have different rules for eligibility, covered benefits, and payment, and the programs have operated as separate and distinct systems despite a growing number of people who depend on both programs for their health care. There is an increasing need to align these programs—and the data and systems that support them—to improve care delivery and the beneficiary experience for dually eligible beneficiaries, while reducing administrative burden for providers, health plans, and states. The interoperability of state and CMS eligibility systems is a critical part of modernizing the programs and improving beneficiary and provider experiences. Improving the accuracy of data on dual eligibility status by increasing the frequency of federal-state data exchanges is a strong first step in improving how these systems work together.

2. Data Exchanges To Support State Buy-in for Medicare Parts A and B

States and CMS routinely exchange data on who is enrolled in Medicare, and which parties are liable for paying that beneficiary's Parts A and B premiums. These data exchanges support state, CMS, and SSA premium accounting, collections, and enrollment functions. Section 1843 of the Act permits states to enter into an agreement with the Secretary to facilitate state ''buy-in,'' that is, payment of Medicare premiums, in this case Part B premiums, on behalf of certain individuals. For those beneficiaries covered under the agreement, the state pays the beneficiary's monthly Part B premium. Section 1818(g) of the Act establishes the option for states to amend their buy-in agreement to include enrollment and payment of the Part A premium for certain specified individuals. All states and the District of Columbia have a Part B buy-in agreement; 36 states and the District of Columbia have a Part A buy-in agreement.

To effectuate the state payment of Medicare Part A or Part B premiums, a state submits data on a buy-in file to CMS via an electronic file transfer (EFT) exchange setup. The state's input file includes a record for each Medicare beneficiary for whom the state is adding or deleting coverage, or changing buy-in status. In response, CMS returns an updated transaction record that provides data identifying, for each transaction on the state file, whether CMS accepted, modified, or rejected it, as well a Part A or Part B billing record showing the state's premium responsibility. In addition, the CMS file may ''push'' new updates obtained from SSA to the state, for example, changes to the Medicare Beneficiary Identifier number or a change of address.

We have issued regulations for certain details of the state buy-in processes. For Medicare Part A, 42 CFR 407.40 describes the option for states to amend the buy-in agreement to cover Part A premiums for Qualified Medicare Beneficiaries (QMBs). For Medicare Part B, 42 CFR 406.26 codifies the process for modifying the buy-in agreement to identify the eligibility groups covered. CMS subregulatory guidance, specifically Chapter 3 of the State Buy-in Manual,[34] specifies that states should exchange buy-in data with CMS at least monthly, but describes the option for states to exchange buy-in data with CMS daily or weekly. Likewise, states can choose to receive the CMS response data file daily or monthly. We note that 31 states and the District of Columbia are now submitting buy-in data to CMS daily; 28 states and the District of Columbia are now receiving buy-in response files from CMS daily.

While many states submit and receive buy-in files daily, some continue to only do so on a monthly basis. We have become increasingly concerned about the limitations of monthly buy-in data exchanges with states. The relatively long lag in updating buy-in data means that the state is not able to terminate or activate buy-in coverage sooner, so the state or beneficiary may be paying premiums for longer than appropriate. In most cases, funds must be recouped and redistributed—a burdensome administrative process involving debits and payments between the beneficiary, state, CMS, and SSA. Additionally, transaction errors do occur in the current data exchange processes. In a monthly exchange, it can take multiple months to correct and resubmit an improperly processed transaction, exacerbating the delays in appropriately assigning premium liability, leading to larger mispayment, recoupment, and redistribution of premiums.

Exchanging the buy-in data with greater frequency supports more timely access to coverage. All states' systems already have the capacity to exchange buy-in data. We acknowledge that states who do not already exchange data daily will need an initial, one-time systems change to do so. However, moving to a daily data exchange would result in a net reduction of burden for states, and further, reduce administrative complexity for beneficiaries and providers. More frequent submission of updates to individuals' buy-in status positively impacts all involved. Based on our experience with the states currently exchanging buy-in data daily, we have found:

- States can terminate buy-in coverage sooner and lower the risk of paying Part A or Part B premiums for individuals once they no longer qualify. Enrollees for whom the buy-in is ending have less risk of a retroactive deduction from their Social Security check due to delayed Part B buy-in terminations (while 42 CFR 407.48(c) limits retroactive recoupments to a maximum of 2 months, an unexpected deduction of up to $268 [2 months of Part B premiums in 2018] is significant for those with incomes low enough to be dually eligible);
- States can detect and fix errors sooner, limiting the impact of such errors;
- State staff can spread the workload of resolving rejected records across the whole month rather than a spike when they receive the monthly CMS response file;
- States can effectuate an earlier shift to Medicare as primary payer for many health care services, for those already covered by Medicaid;
- Beneficiaries newly eligible for buy-in who had been paying premiums themselves can stop having the Part B

[33] As noted above, to the extent other commercial market issuers incur similar costs for coverage sold in the individual or group markets outside of an FFE, those expenses may similarly qualify as QIA.

[34] CMS, ''State Buy-In Manual Chapter 3—Data Exchange,'' *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/buyin_c03.pdf.* (last accessed September 26, 2018).

premium deducted from their Social Security check sooner; and,

• Beneficiaries newly eligible for buy-in who could not afford Medicare premiums can access Medicare Parts A and B services and providers can be assured of coverage sooner.

While there exist opportunities to modernize the platform for buy-in data exchange, we believe that an important first step is to promote the exchange of the most current available data. Section 1843(f) of the Act specifies that Part B buy-in agreements shall contain such provisions as will facilitate the financial transactions of the State and the carrier with respect to deductions, coinsurance, and otherwise, and as will lead to economy and efficiency of operation. Further, section 1818(g)(2)(A) of the Act on Part A buy-in identifies this section 1843(f) requirement as applicable to Part A buy-in. While the regulations governing buy-in agreements (see 42 CFR 406.26 and 407.40) are silent on the frequency of buy-in data exchanges, current guidance articulates that the required buy-in data may be submitted daily, weekly, or monthly. We are proposing to establish frequency requirements in the regulations at 42 CFR 406.26(a)(1) and 407.40(c) to require all states to participate in daily exchange of buy-in data to CMS, with ''daily'' meaning every business day, but that if no new transactions are available to transmit, data would not need to be submitted on a given business day. We believe these requirements will improve the economy and efficiency of operation of the ''buy-in'' process. We propose that states would be required to begin participating in daily exchange of buy-in data with CMS by April 1, 2022. We believe this effective date will allow states to phase in any necessary operational changes or bundle this required change with any new systems implementation. There are 19 states that we anticipate will need to make a system change to send buy-in data to CMS daily, and 22 states that we anticipate will need to make a system change to receive buy-in data from CMS daily. We estimate the one-time cost to be a little less than $80,000 per state, per change. So a state that needs to make systems updates to both send buy-in data daily, and receive buy-in data daily would have a one-time cost of just under $160,000. We seek comment on these proposals.

3. Exchange of State MMA Data Files

States submit data on files at least monthly to CMS to identify all dually eligible individuals, including full-benefit and partial-benefit dually eligible beneficiaries (that is, those who get Medicaid help with Medicare premiums, and often for cost-sharing). The file is called the ''MMA file,'' but is occasionally referred to as the ''State Phasedown file.'' The MMA file was originally developed to meet the need to timely identify dually eligible beneficiaries for the then-new Medicare Part D prescription drug benefit. The Medicare Modernization Act (MMA) established that beginning January 1, 2006, Medicare would be primarily responsible for prescription drug coverage for full-benefit dually eligible individuals; established auto-enrollment of full-benefit dually eligible beneficiaries into Medicare prescription drug plans (with regulations further establishing facilitated enrollment into prescription drug plans for partial-benefit dually eligible beneficiaries), provided that dually eligible beneficiaries are treated as eligible for the Medicare Part D Low Income Subsidy (LIS), sometimes called Extra Help; defined phased down state contributions to partly finance Part D costs for dually eligible beneficiaries; and required risk-adjusting capitation payments for low-income subsidy (which include dually eligible) enrollees of Part D plans. To support these new requirements, we issued 42 CFR 423.910, establishing monthly reporting by states, in which states would submit, at least monthly, a data file identifying dually eligible individuals in their state. Over time, we used these files' data on dual eligibility status to support Part C capitation risk-adjustment, and most recently, to feed dual eligibility status to Part A and B eligibility and claims processing systems so providers, suppliers, and beneficiaries have accurate information on beneficiary cost-sharing obligations.

It is required at 42 CFR 423.910 that states to submit at least one MMA file each month. However, states have the option to submit multiple MMA files throughout the month (up to one per day). Most states submit MMA data files at least weekly; however, only 13 states submit MMA data files daily. As CMS now leverages MMA data on dual eligibility status into systems supporting all four parts of the Medicare program, it is becoming even more essential that dual eligibility status is accurate and up-to-date. Dual eligibility status can change at any time in a month. Waiting up to a month for status updates can negatively impact access to the correct level of benefit at the correct level of payment. Based on our experience with states that exchange data daily, more frequent MMA file submissions benefit states, beneficiaries, and providers, in a number of ways including:

• Enabling an earlier transition to Medicare coverage for prescription drugs, which reduces the number of claims the state pays erroneously and has to recoup from pharmacists (that then have the burden of reaching out to reconcile with the new Part D plan);

• Effectuating an earlier shift to Medicare as primary payer for many health care services;

• Aiding timely error identification and resolution, mitigating the payment and other implications of the error;

• Supporting states that promote enrollment in integrated care by expediting the enrollment into Medicare, since beneficiaries must have Medicare Parts A and B, as well as Medicaid to be eligible for integrated products such as Dual-eligible Special Needs Plans, Medicare-Medicaid Plans, and the Programs for All-inclusive Care for the Elderly (PACE);

• Supporting beneficiaries to obtain access to Medicare Part D benefits and related subsidies sooner, as dual eligibility status on the MMA file prompts CMS to deem individuals automatically eligible for the Medicare Part D LIS and make changes to LIS status (for example, reducing copayments to $0 when data indicate a move to a nursing facility or use of home and community based long term care services) and auto-enroll them into Medicare prescription drug coverage back to the start of dual eligibility status; and,

• Promoting protections for QMBs by improving the accuracy of data for providers and QMBs on zero cost-sharing liability for services under Medicare Parts A and B.

As noted, current regulation requires that the MMA files be submitted at least monthly. We have implemented ''work-arounds'' for lags in dual eligibility status for Part D, including the ''Best Available Evidence'' policy (see 42 CFR 423.800(d)), as well as the Limited Income Newly Eligible Transition demonstration, which provides short term drug coverage for dually eligible beneficiaries with no Part D plan enrollment in a given month (see Medicare Prescription Drug Benefit Manual, Chapter 3, Section 40.1.4).[35] While these work-arounds provide needed protections, more frequent data

[35] CMS, ''Medicare Prescription Drug Benefit Manual: Chapter 3—Eligibility, Enrollment and Disenrollment (2017),'' *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicarePresDrugEligEnrol/Downloads/CY_2018_PDP_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf* (last accessed September 26, 2018).

exchanges would mitigate the need for them.

Ensuring information on dual eligibility status is accurate and up-to-date by increasing the frequency of federal-state data exchange is an important step in the path to interoperability. As a result, we are proposing to update the frequency requirements in 42 CFR 423.910(d) to require that starting April 1, 2022, all states submit the required MMA file data to CMS daily, and to make conforming edits to 42 CFR 423.910(b)(1). Daily would mean every business day, but that if no new transactions are available to transmit, data would not need to be submitted on a given business day. We propose that states will be required to begin submitting these data daily to CMS by April 1, 2022, because we believe this effective date will allow states to phase in any necessary operational changes or bundle this required change with any new systems implementation. There are 37 states and the District of Columbia that we anticipate will need to make a system change to send MMA data to CMS daily. We estimate the one-time cost for a state to be a little less than $80,000 for this MMA data systems change. For a detailed discussion of the costs associated with these requirements we refer readers to section XVI. of this proposed rule. We seek comment on these proposals.

B. Request for Stakeholder Input

In addition to the proposals recommended above, we seek public comment for consideration in future rulemaking on how we can achieve greater interoperability of federal-state data for dually eligible beneficiaries, including in the areas of program integrity and care coordination, coordination of benefits and crossover claims, beneficiary eligibility and enrollment, and their underlying data infrastructure. Specifically, we seek comment on:

- Whether existing regulations, as well as those proposed here, sufficiently support interoperability among those serving dually eligible beneficiaries, and if not, what additional steps would advance interoperability.
- How to enhance the interoperability of existing CMS processes to share Medicare data with states for care coordination and program integrity.
- How to improve the CMS and state data infrastructure to support interoperability (for example, more frequent data exchanges, common data environment, etc.).
- For eligibility, how interoperability can provide timely, integrated eligibility and enrollment status across Medicare, Medicaid, and related agencies (for example, SSA), and reduce the need for persons to provide, and states to collect/process, the same demographic information (for example, address, income).
- For provider enrollment in both Medicaid and Medicare, how interoperability can streamline provider enrollment and reduce provider and state burden to increase systems accuracy and beneficiary utilization of provider enrollment data (for example, disability competence, hours of service, types of insurance accepted, etc.).
- For coordination of benefits, including crossover claims, the underlying changes that would need to be made to support interoperability (for example, coding, file formats, provider/beneficiary identifier, and encounter versus FFS data).

Please include specific examples when possible while avoiding the transmission of protected information. Please also include a point of contact who can provide additional information upon request.

VIII. Information Blocking Background and Public Reporting

A. Information Blocking Background

1. Legislative Background and Policy Considerations

The nature and extent of information blocking has come into focus in recent years. In 2015, at the request of the Congress, ONC submitted a Report on Health Information Blocking [36] (hereinafter referred to as the ''Information Blocking Congressional Report''), in which ONC commented on the then current state of technology, health IT, and health care markets. Notably, ONC observed that prevailing market conditions create incentives for some individuals and entities to exercise their control over electronic health information in ways that limit its availability and use. Since that time, ONC and other divisions of HHS have continued to receive feedback regarding practices which may constitute information blocking from patients, clinicians, health care executives, payers, app developers and other technology companies, registries and health information exchanges, professional and trade associations, and many other stakeholders. Despite significant public and private sector efforts to improve interoperability and data liquidity, engagement with stakeholders confirms that adverse incentives remain and continue to undermine progress toward a more connected health system.

Based on these economic realities and first-hand experience working with the health IT industry and stakeholders, ONC concluded in the Information Blocking Congressional Report that information blocking is a serious problem and recommended that the Congress prohibit information blocking and provide penalties and enforcement mechanisms to deter these harmful practices.

MACRA became law in the same month that the Information Blocking Congressional Report was published. Section 106(b)(2)(A) of MACRA amended section 1848(o)(2)(A)(ii) of the Act to require that an eligible professional must demonstrate that he or she has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology, as part of being a meaningful EHR user. Section 106(b)(2)(B) of MACRA made corresponding amendments to section 1886(n)(3)(A)(ii) of the Act for eligible hospitals and, by extension, under section 1814(l)(3) of the Act for CAHs. Sections 106(b)(2)(A) and (B) of MACRA provide that the manner of this demonstration is to be through a process specified by the Secretary, such as the use of an attestation. To implement these provisions, as discussed further below, we established and codified attestation requirements to support the prevention of information blocking, which consist of three statements containing specific representations about a health care provider's implementation and use of CEHRT. To review our discussion of these requirements, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77028 through 77035).

Recent empirical and economic research further underscores the complexity of the information blocking problem and its harmful effects. In a national survey of health information organizations, half of respondents reported that EHR developers routinely engage in information blocking, and a quarter of respondents reported that hospitals and health systems routinely do so.[37] Perceived motivations for

[36] ONC, Report to Congress on Health Information Blocking (Apr. 2015), *https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf.*

[37] *See, for example,* Julia Adler-Milstein and Eric Pfeifer, *Information Blocking: Is It Occurring And What Policy Strategies Can Address It?,* 95 Milbank Quarterly 117, 124–25 (Mar. 2017), available at *http://onlinelibrary.wiley.com/doi/10.1111/1468-0009.12247/full.*

information blocking described by respondents included, for EHR vendors, maximizing short term revenue and competing for new clients, and for hospitals and health systems, strengthening their competitive position relative to other hospitals and health systems. Other research suggests that these practices weaken competition among health care providers by limiting patient mobility, encouraging consolidation, and creating barriers to entry for developers of new and innovative applications and technologies that enable more effective uses of clinical data to improve population health and the patient experience.[38]

In December 2016, section 4004 of the Cures Act added section 3022 of the PHSA (the ''PHSA information blocking provision''), which defines conduct by health care providers, health IT developers, and health information exchanges and networks, that constitutes information blocking. The PHSA information blocking provision was enacted in response to ongoing concerns that some individuals and entities are engaging in practices that unreasonably limit the availability and use of electronic health information for authorized and permitted purposes (see the definition of electronic health information proposed by ONC for HHS adoption at 45 CFR 171.102 (published elsewhere in this issue of the **Federal Register**)). These practices undermine public and private sector investments in the nation's health IT infrastructure and frustrate efforts to use modern technologies to improve health care quality and efficiency, accelerate research and innovation, and provide greater value and choice to health care consumers.

The information blocking provision added to PHSA defines and creates possible penalties and disincentives for information blocking in broad terms, working to deter the entire spectrum of practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. The PHSA information blocking provision applies to health care providers, health IT developers, exchanges, and networks. The information blocking provision added to PHSA by the Cures Act also provides that the ''Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of the definition at section 3022(a)(1) of the PHSA.'' ONC has taken the lead on this rulemaking effort, and in addition to the attestation discussed in this section, all health care providers would also be subject to the separate information blocking regulations proposed by ONC for HHS adoption at 45 CFR part 171 (published elsewhere in this issue of the **Federal Register**).

We propose to publicly report certain information about eligible clinicians' attestations under the QPP on Physician Compare and eligible hospitals' and CAHs' attestations under the Medicare FFS Promoting Interoperability Program (previously known as the Medicare EHR Incentive Program) on a CMS website. As discussed below, although we have already implemented what is required by sections 106(b)(2)(A) and (B) of MACRA through the attestation requirements we have established in prior rulemaking (81 FR 77028 through 77035), we believe publishing information on which eligible clinicians, eligible hospitals, and CAHs have negatively attested that they have not knowingly and willfully taken action to limit or restrict the compatibility or interoperability of certified EHR technology would serve to discourage knowing and willful behavior that limits interoperability and prevents the sharing of information discussed in both MACRA and the Cures Act.

B. Public Reporting and Prevention of Information Blocking on Physician Compare

Physician Compare (*http://www.medicare.gov/physiciancompare*) draws its operating authority from section 10331(a)(1) of the Affordable Care Act. Consistent with section 10331(a)(2) of the Affordable Care Act, Physician Compare initiated a phased approach to publicly reporting performance scores that provide comparable information on quality and patient experience measures. A complete history of public reporting on Physician Compare is detailed in the CY 2016 Physician Fee Schedule (PFS) final rule with comment period (80 FR 71117 through 71122). More information about Physician Compare, including the history of public reporting and regular updates about what information is currently available, can also be accessed on the Physician Compare Initiative website at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/.*

As discussed in the CY 2018 Quality Payment Program final rule (82 FR 53820), Physician Compare has continued to pursue a phased approach to public reporting under MACRA in accordance with section 1848(q)(9) of the Act. Specifically, subparagraphs (A) and (D) of section 1848(q)(9) of the Act facilitate the continuation of the phased approach to public reporting by requiring the Secretary to make available on the Physician Compare website, in an easily understandable format, individual MIPS eligible clinician and group performance information, including: The MIPS eligible clinician's final score; the MIPS eligible clinician's performance under each MIPS performance category (quality, cost, improvement activities, and Promoting Interoperability); names of eligible clinicians in Advanced APMs and, to the extent feasible, the names of such Advanced APMs and the performance of such models; and, aggregate information on the MIPS, posted periodically, including the range of final scores for all MIPS eligible clinicians and the range of the performance of all MIPS eligible clinicians for each performance category.

In the CY 2018 Quality Payment Program final rule (82 FR 53827), we finalized a policy to include an indicator on Physician Compare, as technically feasible, for any eligible clinician or group who successfully meets the Promoting Interoperability performance category. We also finalized a policy to include, as technically feasible, additional information on Physician Compare, either on the profile pages or in the downloadable database, including, but not limited to objectives, activities, or measures specified in the CY 2018 Quality Payment Program final rule (82 FR 53827; see 82 FR 53663 through 53688) with respect to the Promoting Interoperability performance category.

Generally, all data available for public reporting on Physician Compare must meet our established public reporting standards under 42 CFR 414.1395(b). In addition, for each program year, CMS provides a 30-day preview period for any clinician or group with QPP data being publicly reported on Physician Compare under 42 CFR 414.1395(d). All data available for public reporting—

[38] *See, for example,* Martin Gaynor, Farzad Mostashari, and Paul B. Ginsberg, *Making Health Care Markets Work: Competition Policy for Health Care,* 16–17 (Apr. 2017), *available at http://heinz.cmu.edu/news/news-detail/index.aspx?nid=3930;* see also Diego A. Martinez et al., *A Strategic Gaming Model For Health Information Exchange Markets,* Health Care Mgmt. Science (Sept. 2016). Niam Yaraghi, *A Sustainable Business Model for Health Information Exchange Platforms: The Solution to Interoperability in Healthcare IT* (2015), available at *http://www.brookings.edu/research/papers/2015/01/30-sustainable-business-model-health-information-exchange-yaraghi;* Thomas C. Tsai & Ashish K. Jha, *Hospital Consolidation, Competition, and Quality: Is Bigger Necessarily Better?,* 312 J. AM. MED. ASSOC. 29, 29 (2014).

such as final scores—are available for review and correction during the targeted review process as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77392).

Building upon the continuation of our phased approach to public reporting and understanding the importance of preventing information blocking, promoting interoperability and the sharing of information, we propose to make certain data about the attestation statements on the prevention of information blocking referenced earlier in section VIII.A. of this proposed rule available for public reporting on Physician Compare, drawing upon our authority under section 10331(a)(2) of Affordable Care Act, which requires us to make publicly available on Physician Compare information on physician performance that provides comparable information for the public on quality and patient experience measures. Section 10331(a)(2) of the Affordable Care Act provides that to the extent scientifically sound measures that are developed consistent with the requirements of section 10331 of the Affordable Care Act are available, such information shall include, to the extent practicable, an assessment of the coordination of care and other information as determined appropriate by the Secretary. We believe section 10331(a)(2) of the Affordable Care Act provides the statutory authority to publicly report certain data about the prevention of information blocking attestation statements as an assessment of care coordination and as other information determined appropriate by the Secretary. Furthermore, the prevention of information blocking attestation statements are required for a clinician to earn a Promoting Interoperability performance category score, which is then incorporated into the final score for MIPS, and we are required to publicly report both of these scores under section 1848(q)(9)(A) of the Act. Publicly posting this information as an indicator is consistent with our finalized policy to publicly report, either on the profile pages or in the downloadable database, other aspects of the Promoting Interoperability performance category, such as objectives, activities, or measures specified in the CY 2018 Quality Payment Program final rule.

There are three prevention of information blocking attestation statements under 42 CFR 414.1375(b)(3)(ii)(A) through (C) to which eligible clinicians reporting on the Promoting Interoperability performance category of MIPS must attest. To report successfully on the Promoting Interoperability performance category, in addition to satisfying other requirements, an eligible clinician must submit an attestation response of ''yes'' for each of these statements. For more information about these statements, we refer readers to the preamble discussion in the CY 2017 Quality Payment Program final rule (81 FR 77028 through 81 FR 77035).

We believe it would benefit the public to know if eligible clinicians have attested negatively to the statements under 42 CFR 414.1375(b)(3)(ii) as this may assist the patient in selecting a clinician or group who collaborates with other clinicians, groups, or other types of health care providers by sharing information electronically, and does not withhold information that may result in better care. Therefore, we are proposing to include an indicator on Physician Compare for the eligible clinicians and groups that submit a ''no'' response to any of the three statements under 42 CFR 414.1375(b)(3)(ii)(A) through (C). In the event that these statements are left blank, that is, a ''yes'' or a ''no'' response is not submitted, the attestations would be considered incomplete, and we would not include an indicator on Physician Compare. We also propose to post this indicator on Physician Compare, either on the profile pages or the downloadable database, as feasible and appropriate, starting with the 2019 performance period data available for public reporting starting in late 2020.

Under 42 CFR 414.1395(b), these data must meet our established public reporting standards, including that to be included on the public facing profile pages, the data must resonate with website users, as determined by CMS. In previous testing with patients and caregivers, we have learned that effective use of CEHRT is important to them when making informed health care decisions. To determine how to best display and meaningfully communicate the indicator on the Physician Compare website, the exact wording and, if applicable, profile page indicator would be determined after user testing and shared with stakeholders through the Physician Compare Initiative page, listservs, webinars, and other available communication channels. We note this proposal is contingent upon the availability of and technical feasibility to use these data for public reporting. We request comment on this proposal.

C. Public Reporting and Prevention of Information Blocking for Eligible Hospitals and Critical Access Hospitals (CAHs)

Section 1886(n)(4)(B) of the Act requires the Secretary to post in an easily understandable format a list of the names and other relevant data, as determined appropriate by the Secretary, of eligible hospitals and CAHs who are meaningful EHR users under the Medicare FFS program, on a CMS website. In addition, that section requires the Secretary to ensure that an eligible hospital or CAH has the opportunity to review the other relevant data that are to be made public with respect to the eligible hospital or CAH prior to such data being made public. We believe certain information related to the prevention of information blocking attestation statements under 42 CFR 495.40(b)(2)(i)(I)(*1*) through (*3*) would constitute other relevant data under section 1886(n)(4)(B) of the Act. Specifically, we are referring to the three prevention of information blocking attestation statements under 42 CFR 495.40(b)(2)(i)(I)(1) through (3) to which eligible hospitals and CAHs must attest for purposes of the Promoting Interoperability Program. As part of successfully demonstrating that an eligible hospital or CAH is a meaningful EHR user for purposes of the Promoting Interoperability Program, the eligible hospital or CAH must submit an attestation response of ''yes'' for each of these statements. For more information about these statements, we refer readers to the preamble discussion in the CY 2017 Quality Payment Program final rule (81 FR 77028 through 81 FR 77035).

We believe it would be relevant to the public to know if eligible hospitals and CAHs have attested negatively to the statements under 42 CFR 495.40(b)(2)(i)(I)(1) through (3) as it could indicate that they are knowingly and unreasonably interfering with the exchange or use of electronic health information in ways that limit its availability and use to improve health care. As we stated in the CY 2017 Quality Payment Program final rule, we believe that addressing issues related to information blocking would require additional and more comprehensive measures (81 FR 77029). In addition, publicly posting this information would reinforce our commitment to focus on increased interoperability and the appropriate exchange of health information. We propose to post information on a CMS website available to the public indicating that an eligible hospital or CAH attesting under the Medicare FFS Promoting

Interoperability Program submitted a ''no'' response to any of the three statements under 42 CFR 495.40(b)(2)(i)(I)(1) through (3). In the event that these statements are left blank, that is, a ''yes'' or a ''no'' response is not submitted, the attestations would be considered incomplete, and we would not post any information related to these attestation statements for that hospital or CAH. We propose to post this information starting with the attestations for the EHR reporting period in 2019, and we expect the information would be posted in late 2020. In accordance with section 1886(n)(4)(B) of the Act, we propose to establish a process for each eligible hospital and CAH to review the information related to their specific prevention of information blocking attestation statements before it is publicly posted on a CMS website. Specifically, for each program year, we propose a 30-day preview period for an eligible hospital or CAH to review this information before it is publicly posted. During the 30-day preview period, we propose that all of the information that we would publicly post would be available for the eligible hospital or CAH to review, and we would consider making changes to the information on a case-by-case basis (for example, in the event the eligible hospital or CAH identifies an error, and we subsequently determine that the information is not accurate). Additional information on the review process will be provided outside of the rulemaking process through the usual communication channels for the program. We invite comments on this proposal.

IX. Provider Digital Contact Information

A. Background

Congress required the Secretary to create a provider digital contact information index in section 4003 of the Cures Act. This index must include all individual health care providers and health care facilities, or practices, in order to facilitate a comprehensive and open exchange of patient health information. Congress gave the Secretary the authority to use an existing index or to facilitate the creation of a new index. In comments received on the FY 2019 IPPS proposed rule RFI, there was strong support for a single, public directory of provider digital contact information. Commenters noted that digital communication could improve interoperability by facilitating efficient exchange of patient records, eliminating the burden of working with scanned paper documents, and ultimately enhancing care coordination.

To ensure the index is accessible to all clinicians and facilities, we have updated the NPPES [39] to be able to capture digital contact information for both individuals and facilities. NPPES currently supplies National Provider Identifier (NPI) numbers to health care providers (both individuals and facilities), maintains their NPI record, and publishes the records online.[40] The Secretary adopted the NPI as the HIPAA administrative simplification standard identifier for health care providers (69 FR 3434). HIPAA covered entities, including health care providers, health plans, and health care clearinghouses, must use the NPI in HIPAA transactions. All health care providers that transmit health information in electronic form in connection with a HIPAA transaction must obtain an NPI.

Health care providers are required to communicate to the NPPES any information that has changed within 30 days of the change (45 CFR 162.410(a)(4)). CMS reviews NPPES to ensure a provider has a valid NPI as part of the Medicare enrollment process, as well as the revalidation process, which occurs every 3 to 5 years depending on the provider or supplier type.

Information in NPPES is publicly accessible via both an online search option and a downloadable database option. As a result, adding digital contact information to this existing index is an efficient and effective way to meet the Congressional requirement to establish a digital contact information index and to promote the sharing of information.

As of June 2018, NPPES has been updated to include the capability to capture one or more pieces of digital contact information that can be used to facilitate secure sharing of health information. For instance, providers can submit a Direct address, which functions similar to a regular email address, but includes additional security measures to ensure that messages are only accessible to the intended recipient in order to keep the information confidential and secure. ''Direct'' is a technical standard for exchanging health information. Direct addresses are available from a variety of sources, including EHR vendors, State Health Information Exchange entities, regional and local Health Information Exchange entities, as well as private service providers offering Direct exchange capabilities called Health Information Service Providers (HISPs) (*https://www.healthit.gov/sites/default/files/directbasicsforprovidersqa_05092014.pdf*). NPPES can also capture information about a wide range of other types of endpoints that providers can use to facilitate secure exchange of health information, for instance a FHIR server URL or query endpoint associated with a health information exchange.

In addition, NPPES can now maintain information about the type of contact information providers and organizations are associated with, along with the preferred uses for each address. Each provider in NPPES can maintain their own unique information or associate themselves with information shared among a group of providers. Finally, NPPES has also added a public API which can be used to obtain contact information stored in the database. Although NPPES is now better equipped to maintain provider digital contact information, many providers have not submitted this information. In the 2015 final rule, ''Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017'' (80 FR 62901), we finalized a policy to collect information in NPPES about the electronic addresses of participants in the EHR Incentive Program (specifically, a Direct address and/or other ''electronic service information'' as available). However, this policy was not fully implemented at the time, in part due to the limitations of the NPPES system which have since been addressed. As a result, many providers have not yet added their digital contact information to NPPES and digital contact information is frequently out of date.

In light of these updates to the NPPES system, all individual health care providers and facilities can take immediate action to update their NPPES record online to add digital contact information. This simple step will significantly improve interoperability by making valuable contact information easily accessible. For those providers who continue to rely on the use of cumbersome, fax-based modes of sharing information, we hope that greater availability of digital contact information will help to reduce barriers to electronic communication with a wider set of providers with whom they share patients. Ubiquitous, public availability of digital contact information for all providers is a crucial step towards eliminating the use of fax machines for the exchange of health information. We urge all providers to take advantage of this resource to implement Congress' requirement that

[39] The NPPES website is available at *https://nppes.cms.hhs.gov/.*

[40] See *https://nppes.cms.hhs.gov/.*

the Secretary establish a digital contact information index.

B. Proposed Public Reporting of Missing Digital Contact Information

Entities seeking to engage in electronic health information exchange need accurate information about the electronic addresses (for example, Direct address, FHIR server URL, query endpoint, or other digital contact information) of potential exchange partners. A common directory of the electronic addresses of health care providers and organizations could enhance interoperability and information exchange by providing a resource where users can obtain information about how to securely transmit electronic health information to a provider.

We propose to increase the number of providers with valid and current digital contact information available through NPPES by publicly reporting the names and NPIs of those providers who do not have digital contact information included in the NPPES system. We propose to begin this public reporting in the second half of 2020, to allow individuals and facilities time to review their records in NPPES and update the system with appropriate digital contact information. We are also requesting comment from stakeholders on the most appropriate way to pursue this public reporting initiative, including where these names should be posted, with what frequency, and any other information stakeholders believe would be helpful.

We believe this information is extremely valuable to facilitate interoperability, and we appreciate Congress' leadership in requiring the establishment of this directory. We are interested in stakeholder comment on additional possible enforcement authorities to ensure that individuals and facilities make their digital contact information publicly available through NPPES. For example, should Medicare reporting programs, such as MIPS, require eligible clinicians to update their NPPES data with their digital contact information? Should CMS require this information to be included as part of the Medicare enrollment and revalidation process? How can CMS work with states to promote adding information to the directory through state Medicaid programs and CHIP? Should CMS require providers to submit digital contact information as part of program integrity processes related to prior authorization and submission of medical record documentation? We will review comments for possible consideration in future rulemaking on these questions.

X. Revisions to the Conditions of Participation for Hospitals and Critical Access Hospitals (CAHs)

A. Background

As noted earlier in this proposed rule, CMS appreciates the pathways Congress has created for action on interoperability and has been working diligently with ONC to implement them. In order to ensure broad stakeholder input to inform our proposals, we published a Request for Information (RFI) on interoperability in several recently published proposed rules, including the FY 2019 IPPS proposed rule (83 FR 20550). Specifically, we published the RFI entitled, ''Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers.'' We requested stakeholders' input on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for long term care facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, we asked for comment on revisions to the current CMS CoPs for hospitals such as: Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and, requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

The RFI discussed several steps we have taken in recent years to update and modernize the CoPs and other health and safety standards to reflect current best practices for clinical care, especially in the area of care coordination and discharge planning. On November 3, 2015, we published a proposed rule, ''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies'' (80 FR 68126), to implement the discharge planning requirements of the IMPACT Act and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, LTCHs, rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals), CAHs, and HHAs must meet in order to participate in the Medicare and Medicaid programs. The final rule in response to public comment on our proposed new requirements for discharge planning for hospitals, CAHs, and HHAs is under development while we review and respond to public comments (our deadline to finalize this rule is November 3, 2019). Several of the proposed requirements from the 2015 Discharge Planning proposed rule directly addressed the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

- Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient's practitioner, if the practitioner is known and has been clearly identified;
- Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/PAC providers, at the time of discharge; and,
- Hospitals, CAHs, and HHAs would need to comply with the IMPACT Act requirements that would require hospitals, CAHs, and certain PAC providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of care and treatment preferences.

We also published the ''Medicare and Medicaid Programs; Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility and Improvement in Patient Care'' proposed rule (81 FR 39448) on June 16, 2016, which is under development while we review and respond to public comments (our deadline to finalize this rule is June 15, 2019). In that rule, we proposed updating a number of CoP requirements that hospitals and CAHs would have to meet to participate in the Medicare and Medicaid programs. One of the proposed hospital CoP revisions directly addressed the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by such patients, if the information is readily producible in

such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable timeframe. Under the proposal, a hospital could not frustrate the legitimate efforts of individuals to gain access to their own medical records and would be required to meet these patient requests as quickly as record keeping systems permit.

In response to the recent RFI in the FY 2019 IPPS proposed rule, many stakeholders supported our goals of increasing interoperability and acknowledged the important role that hospital settings play in supporting care coordination. Stakeholders agreed that use of electronic technology was an important factor in ensuring safe transitions. At the same time, many stakeholders expressed concerns about implementing policy changes within the CoPs, which may increase the compliance burden on hospitals.

Given responses to the recent RFI, as well as previous rulemaking activities, we are seeking to further expand CMS requirements for interoperability within the hospital and CAH CoPs as part of this proposed rulemaking by focusing on electronic patient event notifications. In addition, we are committed to taking further steps to ensure that facilities that are electronically capturing information are electronically exchanging that information with providers who have the capacity to accept it. We expect that this will be required through rulemaking at a future point in time, with one option being alignment with the TEFCA described in section 4003 of the Cures Act. We will also continue to consider the RFI responses as we pursue this goal in future rulemaking.

Infrastructure supporting the exchange of electronic health information across settings has matured substantially in recent years. Research studies have increasingly found that health information exchange interventions can effect positive outcomes in health care quality and public health, in addition to more longstanding findings around reductions in utilization and costs. A recent review of how health information exchange interventions can improve cost and quality outcomes identified a growing body of high-quality studies showing that these interventions are associated with beneficial results.[41] The authors identified a number of studies demonstrating positive effects on outcomes associated with better care coordination, such as reductions in 30-day readmissions,[42] [43] [44] and medication reconciliation.[45]

Electronic patient event notifications from hospitals, or clinical event notifications, are one type of health information exchange intervention that has been increasingly recognized as an effective and scalable tool for improving care coordination across settings, especially for patients at discharge. This approach has been identified with a reduction in readmissions following implementation.[46] We note that the evidence cited in this section to support the use of innovative health information exchange interventions and approaches, such as the patient event notifications that we are proposing to require in this rule, can be applied to various types of hospitals, including psychiatric hospitals, as well as to CAHs, as discussed below.

Patient event notifications are automated, electronic communications from the discharging provider to another facility, or to another community provider as identified by the patient, which alerts the receiving provider that the patient has received care at a different setting. Depending on the implementation, information included with these notifications can range from conveying the patient's name, other basic demographic information, and the sending institution to a richer set of clinical data on the patient. Regardless of the information included, these notifications can help ensure that a receiving provider is aware that the patient has received care elsewhere. The notification triggers a receiving provider to reach out to the patient and deliver appropriate follow-up care in a timely manner. By notifying the physician, care manager, or care management team, the notification can help to improve post-discharge transitions and reduce the likelihood that a patient would face complications from inadequate follow-up care.

In addition to their effectiveness in supporting care coordination, virtually all EHR systems generate the basic messages commonly used to support electronic patient event notifications. These notifications are based on admission, discharge, and transfer (ADT) messages, a standard message used within an EHR as the vehicle for communicating information about key changes in a patient's status as they are tracked by the system (more information about the current standard supporting these messages is available at *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=144*). As noted in the ISA published by ONC, this messaging standard has been widely adopted across the health care system (see *https://www.healthit.gov/isa/sending-a-notification-a-patients-admission-discharge-andor-transfer-status-other-providers*).

ADT messages provide each patient's personal or demographic information (such as the patient's name, insurance, next of kin, and attending physician), when that information has been updated, and also indicate when an ADT status has changed. To create an electronic patient event notification, a system can use the change in ADT status to trigger a message to a receiving provider or to a health information exchange system that can then route the message to the appropriate provider. In addition to the basic demographic information contained in the ADT message, some patient event notification implementations attach more detailed information to the message regarding the patient's clinical status and care received from the sending provider.

B. Proposal for Hospitals (Proposed 42 CFR 482.24(d))

We propose to revise the CoPs for Medicare- and Medicaid-participating hospitals at 42 CFR 482.24 by adding a new standard at paragraph (d), ''Electronic Notifications,'' that would require hospitals to send electronic patient event notifications of a patient's admission, discharge, and/or transfer to another health care facility or to another community provider. As noted in the

[41] Menachemi N, Rahurkar S, Harle CA, Vest JR, The benefits of health information exchange: An updated systematic review, J Am Med Inform Assoc. 2018 Apr 28, accessed at *https://www.ncbi.nlm.nih.gov/pubmed/29718258.*

[42] Yeaman B, Ko KJ, Alvarez del Castillo R. Care ransitions in long-term care and acute care: Health information exchange and readmission rates. Online J Issues Nurs 2015;20(3):5. Accessed at *https://www.ncbi.nlm.nih.gov/pubmed/26882514.*

[43] Vest JR, Kern LM, Silver MD, Kaushal R, investigators H. The potential for community-based health information exchange systems to reduce hospital readmissions. J Am Med Inform Assoc, 2015 March, accessed at *https://www.ncbi.nlm.nih.gov/pubmed/25100447.*

[44] Unruh MA, Jung HY, Kaushal R, Vest JR, Hospitalization event notifications and reductions in readmissions of Medicare FFS beneficiaries in the Bronx, New York. J AM Med Inform Assoc, 2017 Apr 1, accessed at *https://www.ncbi.nlm.nih.gov/pubmed/28395059.*

[45] Boockvar KS, Ho W, Pruskowski J, et al. Effect of health information exchange on recognition of medication discrepancies is interrupted when data charges are introduced: Results of a cluster-randomized controlled trial. J Am Med Inform Assoc 2017, accessed at *https://www.ncbi.nlm.nih.gov/pubmed/28505367.*

[46] Unruh MA, Jung HY, Kaushal R, Vest JR, Hospitalization event notifications and reductions in readmissions of Medicare FFS beneficiaries in the Bronx, New York. J AM Med Inform Assoc, 2017 Apr 1, accessed at *https://www.ncbi.nlm.nih.gov/pubmed/28395059.*

discussion above, we would require hospitals to convey, at a minimum, the patient's basic personal or demographic information, as well as the name of the sending institution (that is, the hospital), and, if not prohibited by other applicable law, diagnosis. We would also encourage hospitals, as their systems and those of the receiving providers allow, to work with patients and their practitioners to offer more robust patient information and clinical data upon request in accordance with applicable law.

For a hospital that currently possesses an EHR system with the capacity to generate the basic patient personal or demographic information for electronic patient event (ADT) notifications, compliance with this proposed standard within the Medical records services CoP (42 CFR 482.24) would be determined by the hospital demonstrating that its system: (1) Is fully operational and that it operates in accordance with all State and Federal statutes and regulations regarding the exchange of patient health information; (2) utilizes the content exchange standard incorporated by reference at 45 CFR 170.299(f)(2); (3) sends notifications that must include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law, patient diagnosis); and (4) sends notifications directly, or through an intermediary that facilitates exchange of health information, and at the time of the patient's admission to the hospital and either immediately prior to or at the time of the patient's discharge and/or transfer from the hospital. We recognize that some existing ADT messages might not include diagnosis and therefore seek comment on the technical feasibility of including this information as well as the challenges in appropriately segmenting this information in instances where the diagnosis may not be permitted for disclosure under other applicable laws.

We propose to limit this requirement to only those hospitals which currently possess EHR systems with the technical capacity to generate information for electronic patient event notifications as discussed below, recognizing that not all Medicare- and Medicaid-participating hospitals have been eligible for past programs promoting adoption of EHR systems. Our goal with this proposed requirement is to ensure that hospital EHR systems have a basic capacity to generate messages that can be utilized for notifications by a wide range of receiving providers, enabled by common standards. We believe that a system that utilizes the ADT messaging standard, which is widely used as the basis for implementing these notifications and other similar use cases, would meet this goal by supporting the availability of information that can be used to generate information for patient event notifications. Specifically, we propose that the system utilize the ADT Messaging standard incorporated by reference at 45 CFR 170.299(f)(2).[47]

While there is no criterion under the ONC Health IT Certification Program which certifies health IT to create and send electronic patient event notifications, this standard is referenced by other certification criteria under the program. Specifically, this standard supports certification criteria related to transferring information to immunization registries, as well as transmission of laboratory results to public health agencies as described at 45 CFR 170.315(f) under the 2015 Edition certification criteria, and at 45 CFR 170.314(f) under the 2014 Edition. Thus, we expect systems that include Health IT Modules certified to meet criteria which reference this standard will possess the basic capacity to generate information for notification messages. We further note that adopting certified health IT that meets these criteria has been required for any hospital seeking to qualify for the Promoting Interoperability Programs (formerly the EHR Incentive Programs).

We recognize that there is currently significant variation in how hospitals have utilized the ADT messages to support implementation of patient event notifications. We also recognize that many hospitals, which have already implemented notifications, may be delivering additional information beyond the basic information included in the ADT message (both automatically when a patient's status changes and then upon request from receiving providers) to receiving practitioners, patient care team members, and post-acute care services providers and suppliers with whom they have established patient care relationships and agreements for patient health information exchange as allowed by law. We believe consensus standards for ADT-based notifications may become more widely adopted in the future (we refer readers to ONC's ISA[48] for more information about standards under consideration). However, at this time, we do not wish to restrict hospitals from pursuing more advanced content as part of patient notifications, nor to create redundant requirements where hospitals already have a suitable notification system in place. Accordingly, while we are requiring that hospitals subject to this proposal possess a system utilizing this standard, hospitals may utilize other standards or features to support their notification systems. We request comment on this proposal, and whether this requirement would achieve the goal of setting a baseline for hospitals' capacity to generate information for electronic notifications, while still allowing for innovative approaches that would potentially increase the effectiveness of these notifications toward improving patient outcomes and safety during transitions in care.

We further propose that the hospital would need to demonstrate that the system's notification capacity is fully operational, that it operates in accordance with all state and federal statutes and regulations regarding the exchange of patient health information. We intend for these notifications to be required, at minimum, for inpatients admitted to, and discharged and/or transferred from the hospital. However, we also note that patient event notifications are an effective tool for coordinating care across a wider set of patients that may be cared for by a hospital. For instance, a patient event notification could ensure a primary care physician is aware that their patient has received care at the emergency room, and initiate outreach to the patient to ensure that appropriate follow-up for the emergency visit is pursued. While we encourage hospitals to extend the coverage of their notification systems to serve additional patients, outside of those admitted and seen as inpatients, we also seek comment on whether we should identify a broader set of patients to whom this requirement would apply, and if so, how we should implement such a requirement in a way that minimizes administrative burden on hospitals.

Additionally, we are proposing that the hospital must demonstrate that its system sends notifications that must include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law, patient diagnosis). The hospital would also need to demonstrate that the system sends notifications directly, or through an intermediary that facilitates exchange of health information, and at the time of the patient's admission to the hospital, to licensed and qualified practitioners, other patient care team members, and

[47] Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), an Application Protocol for Electronic Data Exchange in Healthcare Environments, February 21, 2007.

[48] *https://www.healthit.gov/isa/admission-discharge-and-transfer.*

PAC services providers and suppliers that: (1) Receive the notification for treatment, care coordination, or quality improvement purposes; (2) have an established care relationship with the patient relevant to his or her care; and (3) for whom the hospital has a reasonable certainty of receipt of notifications. Similarly, we are also proposing that the hospital would need to demonstrate the transmission of these notifications either directly, or through an intermediary that facilitates the exchange of health information, and either immediately prior to or at the time of the patient's discharge or transfer from the hospital, to licensed and qualified practitioners, other patient care team members, and PAC services providers and suppliers that: (1) Receive the notification for treatment, care coordination, or quality improvement purposes; (2) have an established care relationship with the patient relevant to his or her care; and (3) for whom the hospital has a reasonable certainty of receipt of notifications. We believe this proposal will allow for a diverse set of strategies that hospitals might use when implementing patient event notifications.

Through these provisions, we are seeking to allow for different ways that a hospital might identify those practitioners, other patient care team members, and PAC services providers and suppliers that are most relevant to both the pre-admission and post-discharge care of a patient. We are proposing that hospitals should send notifications to those practitioners or providers that have an established care relationship with the patient relevant to his or her care. We recognize that hospitals and their partners may identify appropriate recipients through various methods. For instance, hospitals might identify appropriate practitioners by requesting this information from patients or caregivers upon arrival, or by obtaining information about care team members from the patient's record. We expect hospitals might develop or optimize processes to capture information about established care relationships directly, or work with an intermediary that maintains information about care relationships. In other cases, hospitals may, directly or through an intermediary, identify appropriate notification recipients through the analysis of care patterns or other attribution methods that seek to determine the provider most likely to be able to effectively coordinate care post-discharge for a specific patient. The hospital or intermediary might also develop processes to allow a provider to specifically request notifications for a given patient for whom they are responsible for care coordination as confirmed through conversations with the patient.

Additionally, we would expect hospitals, psychiatric hospitals, and CAHs to comply with the Health Insurance Portability and Accountability Act (HIPAA) privacy rules set out at 45 CFR parts 160 and 164 when these proposed CoP requirements for patient event notifications are finalized. As required at 42 CFR 482.11 for hospitals and psychiatric hospitals and at 42 CFR 485.608 for CAHs, these providers must comply with all pertinent currently existing federal laws, including the HIPAA Privacy Rule. The patient event notifications and other exchanges of patient information would be permitted as disclosures for treatment purposes under 45 CFR part 164.

We also recognize that factors outside of the hospital's control may determine whether or not a notification is successfully received and utilized by a practitioner. Accordingly, we have proposed that a hospital would only need to send notifications to those practitioners for whom the hospital has reasonable certainty of receipt. While we expect hospitals will, to the best of their ability, seek to ensure that notification recipients are able to receive notifications (for instance, by obtaining a recipient's Direct address), we understand that technical issues beyond the hospital's control may prevent successful receipt and use of a notification.

Finally, we note that hospitals have an existing responsibility under the CoPs at 42 CFR 482.43(d) to ''transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.'' We wish to emphasize that our proposal regarding patient event notifications would be separate from the requirement regarding necessary medical information at 42 CFR 482.43(d). We recognize that processes to implement this proposal, if finalized, may intersect with the hospital's discharge planning process. We note that nothing in this proposal would affect the hospital's responsibilities under 42 CFR 482.43(d). However, if this proposal is finalized, hospitals may wish to consider ways to fulfill these requirements in ways that reduce redundancy while still remaining compliant with existing requirements. For instance, where appropriate and allowed by law, hospitals may seek to include required necessary medical information within the same message as a patient event notification.

As previously stated, we are committed to continuing to identify further steps we can take to ensure that facilities that are electronically capturing information are exchanging that information electronically with providers that have the capacity to accept it. We expect that this will be required through rulemaking at a future point in time with one option being alignment with the TEFCA described in the Cures Act.

C. Proposal for Psychiatric Hospitals (Proposed 42 CFR 482.61(f))

Medicare- and Medicaid-participating psychiatric hospitals must comply with all of the hospital CoPs at 42 CFR 482.1 through 482.23 and at 42 CFR 482.25 through 482.57. They also must adhere to special provisions regarding medical records at 42 CFR 482.61 and staffing requirements at 42 CFR 482.62. Since the medical records requirements are different for psychiatric hospitals, and since these hospitals do not have to comply with our regulations at 42 CFR 482.24, we are proposing a new electronic notification standard at 42 CFR 482.61(f) within the special provisions for psychiatric hospitals in this section.

Similar to our proposal for hospitals at 42 CFR 482.24(d), we are proposing a new standard at 42 CFR 482.61(f), ''Electronic Notifications,'' that would require psychiatric hospitals to send electronic patient event notifications of a patient's admission, discharge, and/or transfer to another health care facility or to another community provider.

As we have proposed for hospitals, we propose to limit this requirement to only those psychiatric hospitals which currently possess EHR systems with the technical capacity to generate information for electronic patient event notifications, defined as systems that utilize the content exchange standard incorporated by reference at 45 CFR 170.299(f)(2). We propose that for a psychiatric hospital that currently possesses an EHR system with the capacity to generate the basic patient personal or demographic information for electronic patient event (ADT) notifications, compliance with this proposed standard within the Special medical records requirements for psychiatric hospitals CoP (42 CFR 482.61) would be determined by the hospital demonstrating that its system: (1) Is fully operational and that it operates in accordance with all State and Federal statutes and regulations regarding the exchange of patient health

information; (2) utilizes the content exchange standard incorporated by reference at 45 CFR 170.299(f)(2); (3) sends notifications that must include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law, patient diagnosis); and (4) sends notifications directly, or through an intermediary that facilitates exchange of health information, and at the time of the patient's admission to the hospital and either immediately prior to or at the time of the patient's discharge and/or transfer from the hospital. Please note that we are requesting comment on this policy as part of this hospital proposal in section X.B. of this proposed rule above. Please see additional discussion in the proposal for hospitals above.

Additionally, we are proposing that the hospital would need to demonstrate that the system sends notifications directly, or through an intermediary that facilitates exchange of health information, and at the time of the patient's admission to the hospital, to licensed and qualified practitioners, other patient care team members, and PAC services providers and suppliers that: (1) Receive the notification for treatment, care coordination, or quality improvement purposes; (2) have an established care relationship with the patient relevant to his or her care; and (3) for whom the hospital has a reasonable certainty of receipt of notifications. Similarly, we are also proposing that the hospital would need to demonstrate the transmission of these notifications either directly, or through an intermediary that facilitates the exchange of health information, and either immediately prior to or at the time of the patient's discharge or transfer from the hospital, to licensed and qualified practitioners, other patient care team members, and PAC services providers and suppliers that: (1) Receive the notification for treatment, care coordination, or quality improvement purposes; (2) have an established care relationship with the patient relevant to his or her care; and (3) for whom the hospital has a reasonable certainty of receipt of notifications.

We refer readers to the extended discussion of these proposals in sections X.A. and B. of this proposed rule. We seek comment on these proposals.

D. Proposal for CAHs

We believe implementation of patient event notifications are also important for CAHs to support improved care coordination from these facilities to other providers in their communities. Therefore, similar to our proposals for the hospital and psychiatric hospital medical records requirements as discussed in the preceding sections, we would revise 42 CFR 485.638, by adding a new standard to the CAH Clinical records CoP at paragraph (d), ''Electronic Notifications.'' This proposed standard would require CAHs to send electronic patient event notifications of a patient's admission, discharge, and/or transfer to another health care facility or to another community provider.

We propose to limit this requirement to only those CAHs which currently possess EHR systems with the technical capacity to generate information for electronic patient event notifications, defined as systems that utilize the content exchange standard incorporated by reference at 45 CFR 170.299(f)(2). We propose that for a CAH that currently possesses an EHR system with the capacity to generate the basic patient personal or demographic information for electronic patient event (ADT) notifications, compliance with this proposed standard within the Clinical records services CoP (42 CFR 485.638) would be determined by the CAH demonstrating that its system: (1) Is fully operational and that it operates in accordance with all State and Federal statutes and regulations regarding the exchange of patient health information; (2) utilizes the content exchange standard incorporated by reference at 45 CFR 170.299(f)(2); (3) sends notifications that must include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law, patient diagnosis); and (4) sends notifications directly, or through an intermediary that facilitates exchange of health information, and at the time of the patient's admission to the CAH and either immediately prior to or at the time of the patient's discharge and/or transfer from the CAH. Please note that we are requesting comment on this policy as part of the hospital proposal above in section X.B. of this proposed rule. Please see additional discussion in the proposal for hospitals above.

Additionally, we are proposing that the CAH would need to demonstrate that the system sends notifications directly, or through an intermediary that facilitates exchange of health information, and at the time of the patient's admission to the CAH, to licensed and qualified practitioners, other patient care team members, and PAC services providers and suppliers that: (1) Receive the notification for treatment, care coordination, or quality improvement purposes; (2) have an established care relationship with the patient relevant to his or her care; and (3) for whom the CAH has a reasonable certainty of receipt of notifications. Similarly, we are also proposing that the CAH would need to demonstrate the transmission of these notifications either directly, or through an intermediary that facilitates the exchange of health information, and either immediately prior to or at the time of the patient's discharge or transfer from the CAH, to licensed and qualified practitioners, other patient care team members, and PAC services providers and suppliers that: (1) Receive the notification for treatment, care coordination, or quality improvement purposes; (2) have an established care relationship with the patient relevant to his or her care; and (3) for whom the CAH has a reasonable certainty of receipt of notifications.

We request comments on all of these proposals. We are especially interested in stakeholder feedback about how these proposals should be operationalized. Additionally, we seek comment on how CMS should implement these proposals as part of survey and certification guidance in a manner that minimizes compliance burden on hospitals, psychiatric hospitals, and CAHs while ensuring adherence with the standards. We are also interested in stakeholder input about a reasonable timeframe for implementation of these proposals for hospitals, psychiatric hospitals, and CAHs, respectively.

XI. Request for Information on Advancing Interoperability Across the Care Continuum

A. Background

Transitions across care settings have been characterized as common, complicated, costly, and potentially hazardous for individuals with complex health needs. Yet despite the need for functionality to support better care coordination, discharge planning, and timely transfer of essential health information, interoperability by certain health care providers such as long term and PAC, behavioral health, and home and community-based services continues to lag behind acute care providers. Research from the Assistant Secretary for Planning and Evaluation (ASPE) and CMS, showed that in 2014, 44 percent of patients discharged from an acute care hospitalization received post-acute services, such as an admission to a SNFs, an IRF or a LTCH, or received HHA services. Specifically, of the 1,260,958 patients that received

post-acute services following an acute care hospitalization, ''. . . 47.8 percent were discharged to a HHA, 42.1 percent to a SNF, 8.4 percent to an IRF, 1.0 percent to a LTCH and .7 percent to LTCH-Site Neutral.'' [49] In addition to the frequency of patients discharged from acute care to PAC, a remarkable number of patients discharged from PAC services receive subsequent care by another PAC provider. For instance, while more current analysis is being finalized, we note that 2012 data from the Post-Acute Care Reform Demonstration (PAC PRD) found, ''67 percent of those discharged to SNFs continued on to additional services. Almost a quarter of them were readmitted to the acute hospital (23.1 percent). Another third (32.7 percent) were discharged from the SNF to a HHA.

In patients with the Acute-SNF-HHA pattern, almost 20 percent (19.9 percent) returned to the acute care hospital within 30 days of discharge from the HHA. Hospital patients discharged to LTCHs and IRFs were also likely to use multiple types of PAC services and a substantial share of these cases were readmitted within 30 days of discharge, ranging from 15.9 percent (LTCH-to-IRF cases) to 42.8 percent (LTCH to SNF cases).'' [50] In examining the home health patterns, it is important to keep in mind that a significant number of the home health population does not come through an acute admission or as part of a post-acute trajectory of care but instead are directly admitted to the HHA from the community. The percentages of PAC use and patterns of multiple transitions reinforce the need for safeguards around transitions of care. These findings also speak to the importance of the interoperable exchange of information necessary to ensure continuity of care, and mitigate the risks of unintended events, such as those associated with medication errors, that can result from inadequate and untimely exchange of information.

Poor patient outcomes, resulting from poor communication and lack of information, have been found to contribute to hospital readmissions, emergency department (ED) visits, and adverse outcomes. A well-documented contributor to this problem is incomplete and missing information for patients with frequent transitions across care settings. While interoperable, bidirectional exchange of essential health information can improve these transitions, many long-term and PAC, behavioral health, and home and community-based service providers have not adopted health IT at the same rate as acute care hospitals. One major contributing factor to this difference in adoption rates can be attributed to the fact that PAC providers were not eligible for the Medicare and Medicaid EHR Incentive Programs (now known as the Promoting Interoperability Programs), which slowed adoption of EHRs and other forms of interoperable health IT for these providers.

National data on EHR adoption and interoperability by these providers is limited. For PAC facilities that do possess EHRs, vendor adoption of interoperable functionality has been slow and uneven. A national survey of SNFs found that 64 percent of facilities used an EHR in 2016, 29 percent of SNFs could send or receive health information, but only 7 percent could send, find, receive, and integrate such information.[51] According to the 2015 National Electronic Health Records Survey (NEHRS), 61.3 percent of psychiatrists were using an EHR, of which 40.8 percent were certified systems.[52] A CDC survey found that 26 percent of residential care communities used EHRs in 2016.[53]

B. Solicitation of Comments

We are soliciting comment on several potential strategies for advancing interoperability across care settings to inform future rulemaking activity in this area.

As discussed above, health IT adoption has lagged in care settings that were not part of the EHR Incentive Programs. We are seeking input on how HHS can more broadly incentivize the adoption of interoperable health IT systems and use of interoperable data across settings such as long-term and PAC, behavioral health, and those settings serving individuals who are dually eligible for Medicare and Medicaid and/or receiving home and community-based services. We invite comment on specific policy strategies HHS could adopt to deliver financial support for technology adoption and use in these settings.

We also recognize that an ongoing challenge to advancing and incentivizing interoperability is the lack of agreed-upon measure concepts with which to gauge how well providers are routinely and effectively engaging in exchange of information across settings. To date, the measurement of interoperability has largely focused on the use of certified technology and the percentage of information exchanged. Expanding the scope of interoperability measurement beyond settings that were eligible for the EHR Incentive Programs is critical as efforts are being made to enable health IT and exchange capabilities across a broader range of care settings. In light of the interest by the stakeholder community to enable interoperability across all providers, HHS is seeking public comment on measure concepts that assess interoperability, including measure concepts that address PAC, behavioral health, home and community-based services, and other provider settings.

A National Quality Forum report on *Quality in Home and Community-Based Services to Support Community Living: Addressing Gaps in Performance Measurement* suggested that new types of measure concepts that assess quality across the continuum of care are needed. Specifically, NQF cited the domain of ''service delivery and effectiveness,'' which encompasses the level to which individuals who use Home and Community Based Services (HCBS) receive services and supports sufficient to meet their needs, as well as the domain of ''person-centered planning and coordination,'' which includes a focus on the level to which services and supports across the health and social service systems are coordinated for individuals who receive HCBS. We seek comment on needed measure development work and quality improvement efforts focused on assuring individuals receive sufficient needed services across the care continuum and that their services are

[49] Ongoing work under contract: HHSP23320095651WC with RTI International.

[50] Gage BJ, Morley MA, Smith LM, Ingber MJ, Deutsch A, Kline TL, Dever JA, Abbate JH, Miller RD, Lyda-McDonald B, Kelleher CA, Garfinkel DB, Manning JR, Murtaugh CM, Stineman MG, Mallinson T. (March, 2012). Post-Acute Care Payment Reform Demonstration: Final Report Volume 2. Prepared for the Centers for Medicare and Medicaid Services. Available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/PAC-PRD_FinalRpt_Vol2of4.pdf.*

[51] Alvarado C, Zook K, Henry J. Electronic Health Record Adoption and Interoperability among U.S. Skilled Nursing Facilities in 2016, Washington, DC, Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services, September 2017. Accessed at *https://www.healthit.gov/sites/default/files/electronic-health-record-adoption-and-interoperability-among-u.s.-skilled-nursing-facilities-in-2016.pdf.*

[52] Yang N, Hing E. Table of Electronic Health Record Adoption and Use among Office-based Physicians in the U.S., by Specialty: 2015 National Electronic Health Records Survey. 2017. Accessed at *https://www.cdc.gov/nchs/data/ahcd/nehrs/2015_nehrs_ehr_by_specialty.pdf.*

[53] QuickStats: Percentage of Residential Care Communities That Use Electronic Health Records, by Community Bed Size—United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:138. DOI: *https://www.cdc.gov/mmwr/volumes/67/wr/mm6704a8.htm?s_cid=mm6704a8_w.*

coordinated.[54] We are also interested in comments on the applicability and feasibility of measure concepts for PAC, behavioral health, home and community-based services as identified in previous ASPE reports [55] [56] and the report, *A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy,* published by the National Quality Forum.[57]

As part of its work under the IMPACT Act, which requires, in part, that certain patient assessment data be standardized and interoperable to allow for exchange of the data among PAC providers and other providers, CMS has defined certain standardized patient assessment data elements [58] and their associated health IT vocabularies across PAC settings. Implementation of these standardized data elements is designed to support more seamless and effective assessment of quality across PAC settings, while also presenting a significant improvement in the ability of these settings to potentially share structured electronic data with other providers across the care continuum.

To enable the bidirectional exchange of this health information, we are seeking public comment on whether hospitals and physicians should adopt the capability to collect and electronically exchange a subset of the same PAC standardized patient assessment data elements (for example, functional status, pressure ulcers/injuries) in their EHRs. As these health care providers have generally been eligible for the EHR Incentive Programs (now known as Promoting Interoperability Programs), many of them would have adopted certified EHR technology and health IT systems, which are required to capture and exchange certain data elements under the ONC Health IT certification program. The set of data which systems must include under the certification program is set to expand in coming years under the USCDI Version 1 ONC has proposed for HHS adoption at 45 CFR 170.213, which would establish a minimum set of data classes that would be required to be interoperable nationwide (see the ONC proposed rule published elsewhere in this issue of the **Federal Register**). The USCDI is designed to be expanded in an iterative and predictable way over time.

We are seeking comment on whether to move toward the adoption of PAC standardized data elements through the expansion of the USCDI process. We are interested in whether the standardized patient assessment data elements that are implemented in CMS PAC assessment instruments in satisfaction of the IMPACT Act would be appropriate. If the full set of such standardized patient assessment data elements is not appropriate, we are seeking comment on whether a subset of these standardized items would be appropriate, and input on which data elements should be prioritized as part of a subset. We are also seeking information on what implementation timeline would be most appropriate for requiring adoption of these data elements in provider and hospital systems under the ONC Health IT Certification Program. We are also seeking comment on the administrative, development, and implementation burden that may be associated with adopting these data elements.

XII. Advancing Interoperability in Innovative Models

A. Promoting Interoperability

CMS plans to utilize Center for Medicare and Medicaid Innovation (''Innovation Center'') authority under section 1115A of the Act to test ways to promote interoperability across the health care spectrum. Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce program expenditures, while preserving or enhancing the quality of care furnished to Medicare and Medicaid beneficiaries and CHIP enrollees. Interoperability and health data sharing are critical to the success of new payment and service delivery models that incentivize high quality, efficient care.

Innovation Center models can include multiple types of health care providers and other entities such as physician group practices, hospitals, PAC facilities, community-based organizations providing community-based long-term care services and supports or non-medical services, and dialysis centers. These types of health care providers furnish care to patients in different care settings, have different health IT systems, and have varied levels of experience with, and access to, EHR technology. The historically disparate and inadequate use of health IT among these providers and other entities has posed challenges to interoperability. Additionally, many of these types of health care providers are not eligible for the Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) and the associated financial incentives for EHR adoption and meaningful use.

We believe Innovation Center models (*https://innovation.cms.gov/*) provide an important lever to advance progress toward interoperability. These models offer unique opportunities to engage with health care providers and other entities in innovative ways and to test concepts that have the ability to accelerate change in the U.S. health care system, including to promote interoperability. One example of CMS's use of Innovation Center Models to promote interoperability is found in the Innovation Center's State Innovation Models (SIM) initiative (*https://innovation.cms.gov/initiatives/state-innovations/*), under which several awards to states are focused on health information exchanges and health IT investment. Another example of this work is found in the Comprehensive Primary Care Plus (CPC+) model

[54] Quality in Home and Community-Based Services to Support Community Living: *https://www.qualityforum.org/Publications/2016/09/Quality_in_Home_and_Community-Based_Services_to_Support_Community_Living__Addressing_Gaps_in_Performance_Measurement.aspx.*

[55] Measurement of Interoperable Electronic Health Care Records Utilization Final Report: *https://aspe.hhs.gov/system/files/pdf/255526/EHRUtilizationReport.pdf.*

[56] Analyzing the Public Benefit Attributable to Interoperable Health Information Exchange: *https://aspe.hhs.gov/system/files/pdf/258851/AnalyzingthePublicBenefitAttributabletoInteroperableHealth.pdf.*

[57] A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy: *https://www.qualityforum.org/Projects/i-m/Interoperability_2016-2017/Final_Report.aspx.*

[58] For more information on the Data Element Library see *https://del.cms.gov/DELWeb/pubHome,* as well as the Data Element Library Training and FAQ at *https://del.cms.gov/DELWeb/pubTrainFAQ.* CMS also provides information and training on the various assessment instruments through which post-acute care providers must submit data. Training on the OASIS instrument can be found on the HH QRP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Training.html*; information related to the training on the IRF PAI is available on the IRF QRP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Training.html*; information related to the training on the LTCH CARE Data Set is available on the LTCH QRP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Training.html*; and information related to the training on the MDS is available on the SNF QRP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Training.html.*

(*https://innovation.cms.gov/initiatives/comprehensive-primary-care-plus*), in which primary care practices use health IT to strengthen their ability to deliver care, with some practices partnering with health IT vendors to implement advanced health IT functionality in their practices, including functionality that promotes interoperability and sharing of electronic health information.

B. Examples of Interoperability-Related Areas of Focus for New Model Development

Examples of how we may focus on interoperability related-issues in future model development may include: Models that incorporate piloting emerging standards; models leveraging non-traditional data in model design (for example, data from schools, data regarding housing and data on food insecurity); and models leveraging technology-enabled patient engagement platforms. The Innovation Center has incorporated non-clinical data in prior models, but anticipates addressing additional uses and types of non-clinical data in future models.

We are now requesting public comment on the following general principles around interoperability within Innovation Center models for integration into new models, through provisions in model participation agreements or other governing documents. In applying these general principles, we intend to be sensitive to the details of individual model design, and the characteristics and capacities of the participants in each specific model.

C. Establishing Principles for Promoting Interoperability in Innovative Model Tests

1. Provide Patients Access to Their Own Electronic Health Information

The MyHealthEData and Medicare Blue Button 2.0 initiatives aim to empower patients by ensuring that they have access to their health care data and can decide how their data is going to be used, all while keeping their data safe and secure. Certain Innovation Center models already require that participants with direct patient interactions provide their patients with electronic access to their health information within 24 hours of any encounter. New Innovation Center models may also require that providers and other health care entities with direct patient interactions provide patients access to their own electronic health information and, upon the patient's authorization, to third party developers via APIs.

2. Promote Trusted Health Information Exchange

Innovation Center model participants may, where appropriate, be required to participate in a trusted exchange network that meets the following criteria:

- The trusted exchange network must be able to exchange PHI in compliance with all applicable state and federal laws across jurisdictions.
- The trusted exchange network must connect both inpatient EHRs and ambulatory EHRs.
- The trusted exchange network must support secure messaging or electronic querying by and between patients, providers and payers.

Additionally, model participants may be required to participate in electronic alerting via one of the standards described in the ISA, II–A: Admission, Discharge, and Transfer published and updated by ONC.

3. Adopt Leading Health IT Standards and Pilot Emerging Standards

Emerging health data standards present new opportunities to exchange more types of health care data between health care providers. Innovation Center model participants, along with their health IT vendors, may pilot new FHIR standards and advance adoption of new data classes in USCDI (for example, psychosocial data) to improve interoperability for care management, quality reporting or other priority use cases. As part of the design and testing of innovative payment and service delivery models, the Innovation Center anticipates taking on a leadership role in developing new or less mature FHIR and supporting more innovative interventions undertaken by states, whenever possible.

D. Request for Stakeholder Input

The Innovation Center seeks public comment on the principles for promoting interoperability in innovative payment and service delivery models described above. Additionally, the Innovation Center is requesting public comment on other ways in which the Innovation Center may further promote interoperability among model participants and other health care providers as part of the design and testing of innovative payment and service delivery models.

XIII. Request for Information on Policies To Improve Patient Matching

A. Background

Through stakeholder feedback such as roundtables, stakeholder meetings, and rulemaking, we have received considerable feedback that the lack of a UPI inhibits interoperability efforts because, without a unique identifier for each patient, the safe and secure electronic exchange of health information is constrained as it is difficult to ensure that the relevant records are all for the same patient. HIPAA required the adoption of a ''unique individual identifier for healthcare purposes,'' commonly referred to as a UPI. At the time HIPAA was enacted, HHS began to consider what information would be needed to develop a rule to adopt a UPI standard. An initial Notice of Intent to issue a proposed rule on requirements for a unique health identifier for individuals was published in the November 2, 1998 **Federal Register** (63 FR 61773 through 61774).

Appreciating the significant privacy and security concerns raised by stakeholders regarding implementing a UPI, Congress included language in the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, enacted October 21, 1998) and in each subsequent Appropriations bill, stating none of the funds made available in this Act may be used to promulgate or adopt any final standard under section 1173(b) of the Act (42 U.S.C. 1320d–2(b)) providing for, or providing for the assignment of, a unique health identifier for an individual (except in an individual's capacity as an employer or a health care provider), until legislation is enacted specifically approving the standard. This language has effectively prohibited HHS from engaging in rulemaking to adopt a UPI standard. Consequently, the Secretary withdrew the Notice of Intent to pursue rulemaking on this issue on August 9, 2000 (*https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=200010&RIN=0938-AI91*).

Although the appropriations language regarding the UPI standard has remained unchanged, in the report accompanying the 2017 appropriations bill, Congress additionally stated, although the Committee continues to carry a prohibition against HHS using funds to promulgate or adopt any final standard providing for the assignment of a unique health identifier for an individual until such activity is authorized, the Committee notes that this limitation does not prohibit HHS from examining the issues around patient matching. Accordingly, the Committee encouraged the Secretary, acting through ONC and CMS, to provide technical assistance to private-sector led initiatives to develop a coordinated national strategy that will

promote patient safety by accurately identifying patients to their health information. (H.R. Rep. No. 114–699, p. 110, *https://www.gpo.gov/fdsys/pkg/CRPT-114hrpt699/pdf/CRPT-114hrpt699.pdf*). Congress has repeated this guidance for 2018 and 2019. This guidance directed HHS to focus on examining issues around patient matching and to provide technical assistance to private sector-led initiatives focusing on a patient matching solution.

In conjunction with ONC, we are posing a request for information regarding how CMS could leverage our program authority to improve patient identification to facilitate improved patient safety, enable better care coordination, and advance interoperability. Inaccurate patient matching can lead to adverse events, compromised safety and privacy, inappropriate and unnecessary care, increased health care costs, and poor oversight of fraud and abuse. We consider this a quality of care and patient safety issue and seek stakeholder input on ways we can incent improvements.

In section 4007 of the 21st Century Cures Act, the Government Accountability Office (GAO) was directed to conduct a study to determine whether ONC and other stakeholders could improve patient matching through various mechanisms, to survey ongoing efforts related to the policies and activities and the effectiveness of such efforts occurring in the private sector, and to evaluate current methods used in certified EHRs for patient matching. The GAO was also tasked with submitting to Congress a report concerning the findings of the study. This report was released in January 2019.[59]

In section I of this proposed rule, we discuss further how patient identification and matching pose challenges to interoperability. We look forward to working with ONC as we review the responses to this RFI in concert with the GAO report to help inform potential appropriate methods to scale best practices and leverage program authority to improve patient matching.

B. Solicitation of Comments

We are soliciting comment on potential strategies to address patient matching. Many stakeholders commenting on the interoperability RFIs included in the various 2019 proposed payment rules, including the FY 2019 IPPS proposed rule (83 FR 20550), indicated that patient matching is a ''core functionality'' of patient identification and necessary to ensure care coordination and the best patient outcomes. Commenters also noted that a consistently used matching strategy could accomplish the original goals of a UPI with a diminished risk to individual privacy and health information security. We solicit comment on how and in what way patient matching does or does not present the same security and privacy risks as a UPI.

We understand the significant health information privacy and security concerns raised around the development of a UPI standard and the current prohibition against using HHS funds to adopt a UPI standard. Recognizing Congress' statement regarding patient matching and stakeholder comments stating that a patient matching solution would accomplish the goals of a UPI, we seek comment on ways for us to continue to facilitate private sector work on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information for future consideration.

We are also seeking comment on how we may leverage our program authority to provide support to those working to improve patient matching. We specifically seek input on the following questions and the potential authority for the requirement:

1. Should CMS require Medicare FFS, MA Plans, Medicaid FFS, Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs (not including SADP issuers), use a patient matching algorithm with a proven success rate of a certain percentage where the algorithm and real world processes associated with the algorithm used are validated by HHS or a 3rd party?

2. Should CMS require Medicare FFS, the MA Plans, Medicaid FFS, Medicaid managed care plans, CHIP FFS, CHIP managed care entities, and QHP issuers in FFEs to use a particular patient matching software solution with a proven success rate of a certain percentage validated by HHS or a 3rd party?

3. Should CMS expand the recent Medicare ID card efforts by requiring a CMS-wide identifier which is used for all beneficiaries and enrollees in health care programs under CMS administration and authority, specifically by requiring any or all of the following:

- That MA organizations, Part D prescription drug plan sponsors, entities offering cost plans under section 1876 of the Act, and other Medicare health plans use the Medicare ID in their plan administration.
- That State Medicaid and CHIP agencies in their FFS or managed care programs use the Medicare ID for dual eligible individuals when feasible.
- That QHP issuers in FFEs use the Medicare ID for their enrollees in the administration of their plans.

4. Should CMS advance more standardized data elements across all appropriate programs for matching purposes, perhaps leveraging the USCDI proposed by ONC for HHS adoption at 45 CFR 170.213.

5. Should CMS complement CMS data and plan data in Medicaid managed care plans (MCOs, PIHPs, and PAHPs), CHIP managed care entities, MA Plans, and QHP issuers in an FFE (not including SADP issuers) with one or more verifying data sources for identity proofing? What potential data source should be considered? What are possible restrictions or limitations to accessing such information?

6. Should CMS support connecting EHRs to other complementary verifying data sources for identity proofing? What potential data source should be considered? What are possible restrictions or limitations to accessing such information?

7. To what extent should patient-generated data complement the patient-matching efforts?

XIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

[59] *https://www.gao.gov/assets/700/696426.pdf.*

A. Background

Health plans should have the ability to exchange data instantly with other payers for care and payment coordination or transitions, and with providers to facilitate more efficient care. Health plans are in a unique position to provide enrollees a complete picture of their claims and encounter data, allowing patients to piece together their own information that might otherwise be lost in disparate systems. To advance our commitment to interoperability, we are proposing new requirements to implement APIs for MA organizations at 42 CFR 422.119, Medicaid FFS at 42 CFR 431.60, CHIP FFS at 42 CFR 457.730, Medicaid managed care at 42 CFR 438.242, CHIP managed care at 42 CFR 457.1233(d), and QHP issuers in FFEs, excluding SADPs at 45 CFR 156.221. These openly published APIs will permit third-party applications to retrieve standardized data for adjudicated claims, encounters with capitated and subcapitated providers, provider remittances, beneficiary cost-sharing, reports of lab test results (depending on whether the plan manages such data), provider directories, and, as applicable, preferred drug lists. We believe that these proposals are designed to empower patients by making sure that they can access their healthcare data, through the use of common technologies, without special effort and in an easily usable digital format. We also expect our API proposals to enable the enrollees in the plans that are subject to our proposal to share their healthcare data. By making claims data readily available and portable to the patient, these initiatives support moving our healthcare system away from a FFS payment system that pays for volume and toward a payment system that pays for value and quality by reducing duplication of services; adding efficiency to provider visits; and, facilitating identification of fraud, waste, and abuse.

B. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for Direct Health and Medical Insurance Carriers (NAICS 524114) (*https://www.bls.gov/oes/current/naics5_524114.htm*). Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—OCCUPATION TITLES AND WAGE RATES

Occupation title	Occupation code	Mean hourly wage (/hr)	Fringe benefit (/hr)	Adjusted hourly wage (/hr)
Administrators and Network Architects	15–1140	$46.35	$46.35	$92.70
Security Engineer	17–2199	50.66	50.66	101.32
Computer and Information Analysts	15–1120	41.98	41.98	83.96
General Operations Mgr	11–1021	72.51	72.51	145.02
Operations Research Analysts	15–2031	37.33	37.33	74.66
Software Developers, Applications	15–1132	45.57	45.57	91.14
Computer and Information Systems Managers	11–3021	71.10	71.10	142.20
General and Operations Mgr	11–1021	72.51	72.51	145.02
Designers	27–1020	29.32	29.32	58.64
Technical Writer	27–3042	32.68	32.68	65.36
Computer Systems Analysts	15–1121	41.59	41.59	83.18
Network and Computer Systems Administrators	15–1142	43.64	43.64	87.28

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonable accurate estimation method.

C. Information Collection Requirements (ICRs)

1. ICRs Regarding MMA File Requirements (42 CFR 423.910)

States submit data on files at least monthly to CMS to identify all dually eligible individuals, including full-benefit and partial-benefit dually eligible beneficiaries (that is, those who get Medicaid help with Medicare premiums, and often for cost-sharing). The file is called the MMA file, but is occasionally referred to as the ''State Phasedown file.'' Section 423.910(d) requires states to submit at least one MMA file each month. However, states have the option to submit multiple MMA files throughout the month (up to one per day). Most states submit at least weekly. This information collection activity is currently approved under OMB control number 0938–0958.

Ensuring information on dual eligibility status is accurate and up-to-date by increasing the frequency of federal-state data exchange is an important step toward interoperability. As a result, we are proposing to update the frequency requirements in 42 CFR 423.910(d) to require that starting April 1, 2022, all states submit the required MMA file data to CMS daily, and to make conforming edits to 42 CFR 423.910(b)(1). Daily would mean every business day, but that if no new transactions are available to transmit, data would not need to be submitted on a given business day. We estimate it would take a computer systems analyst about 6 months (approximately 960 hours) to complete the systems updates necessary to process and submit the MMA data daily. As only 13 states currently submit MMA data daily, we estimate a one-time burden for 37 states and the District of Columbia complying with submission of daily MMA data at 3,034,406 (38 states (and DC) × 960 hours × 83.18 per hour for a computer system analyst). We will be revising the information collection request currently approved under 0938–0958 to include the requirements discussed in this section.

2. ICRs Regarding API Proposals (42 CFR 422.119, 431.60, and 438.242, and 45 CFR 156.221)

To promote our commitment to interoperability, we are proposing new requirements for APIs for MA organizations at 42 CFR 422.119, Medicaid FFS at 42 CFR 431.60, CHIP FFS at 42 CFR 457.730, Medicaid managed care at 42 CFR 438.242, CHIP managed care at 42 CFR 457.1233(d), and QHP issuers in FFEs at 45 CFR

156.221. These openly published APIs will permit third-party applications to retrieve standardized data for adjudicated claims, encounters with capitated and subcapitated providers, provider remittances, beneficiary cost-sharing, reports of lab test results, provider directories, and preferred drug lists. To implement the new requirements for APIs, we estimate that plans and states will conduct three major work phases: Initial design; development and testing; and long-term support and maintenance.

In the initial design phase, we believe tasks would include: Determining available resources (personnel, hardware, cloud space, etc.); assessing whether to use in-house resources to facilitate an API connection or contract the work to a third party; convening a team to scope, build, test, and maintain the API; performing a data availability scan to determine any gaps between internal data models and the data required for the necessary FHIR resources; and, mitigating any gaps discovered in the available data.

During the development and testing phase, we believe plans and states would need to conduct the following: Map existing data to FHIR, which would constitute the bulk of the work required for implementation; allocate hardware for the necessary environments (development, testing, production); build a new FHIR server or leverage existing FHIR servers; determine the frequency and method by which internal data is populated on the FHIR server; build connections between the databases and FHIR server; perform capability and security testing; and vetting third-party applications.

After the completion of the API development, we believe that plans and states would need to conduct the following on an annual basis: Allocate resources to maintain the FHIR server, and perform capability and security testing.

The burden estimate related to the new requirements for APIs reflects the time and effort needed to collect the information described above and disclose this information. We estimate an initial set one-time costs associated with the implementing the API requirements. We presume that it will take administrators and network architects 1440 hours (at 92.70 an hour), security engineers 960 hours (at 101.32 an hour), computer and information analysts 480 hours (at 83.96 an hour), operations research analysts 960 hours (at 74.66 an hour), software developers 960 hours (at 91.14 an hour), computer and information systems managers 720 hours (at 142.20 an hour), general and operations managers 720 hours (at 145.02 an hour), designers 960 hours (at 58.64 an hour), technical writers 240 hours (at 65.36 an hour), and computer systems analysts 960 hours (at 83.18 an hour). We estimate a one-time burden assessment of 8,400 (1440hrs + 960hrs + 480hrs + 960hrs + 960hrs + 720hrs + 720hrs + 960hrs + 240hrs + 960hrs) hours per organization or state and a total of 3,898,000 (8,400hrs × 345 organizations) hours across all organizations or states. The one-time cost to implement API requirements is 789,356.00 per organization or state per implementation and 275,432,820 across all organizations or states to complete the task described above.

Once the API is established, we believe that there would be an annual cost for performing necessary capability and security testing, performing necessary upgrades and vetting of third-party applications. We presume that it would take administrators and network architects 180 hours (at 92.70 an hour), network and computer systems administrators 420 hours (at 87.28 an hour), security engineers 240 hours (at 101.32 an hour), computer and information analysts 60 hours (at 83.96 an hour), operations research analysts 120 hours (at 74.66 an hour), software developers 240 hours (at 91.14 an hour), computer and information systems managers 90 hours (at 142.20 an hour), general and operations managers 90 hours (at 145.02 an hour), designers 120 hours (at 58.64 an hour), technical writers 30 hours (at 65.36 an hour), and computer systems analysts 120 hours (at 83.96 an hour). We estimate the total annual burden to be 1,710 hours (180hrs + 420hrs + 60hrs + 120hrs + 240hrs + 90hrs + 120hrs + 30hrs + 120hrs) per organization or state, and 589,950 hours (1,710hrs × 345 organizations) across all organizations and states. Thus, the total annual cost to maintain the API requirements is 158,359.80 per organization or state and 54,634,131 across all organizations and states.

3. Summary of Information Collection Burdens

TABLE 2—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation Section(s)	OMB Control Number	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
§ 423.910	0938–0958 *	38	38	20	960	83.18	3,034,406	0	3,034,406
§ 422.119, § 431.60, § 457.730, § 438.242, § 457.1233 and § 156.221.	0938–New	345	345	840	2,889,600	.....	275,432,820	0	275,432,820
§ 422.119, § 431.60, § 457.730, § 438.242, § 457.1233, and § 156.221.	0938–New	345	345	1,710	588,240	.....	54,634,131	0	54,634,131
Total	.....	344	344	2,570	3,478,800	.....	333,101,357	.....	333,101,357

* This currently approved ICR will be revised to include the burden discussed in this rule.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by May 3, 2019.

D. Exempt ICRs

1. Usual and Customary Business Practices

While the requirements under 42 CFR 482.24(d), 482.61(f) and 485.638 are subject to the PRA, we believe the burden associated with those requirements is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons during the normal course of their activities, and therefore, should be considered usual and customary business practices.

We are proposing to further expand CMS requirements for interoperability within the hospital, psychiatric hospital, and CAH CoPs by focusing on electronic patient event notifications.

For hospitals, psychiatric hospitals, and CAHs, we are proposing similar requirements to revise the CoPs for Medicare- and Medicaid-participating hospitals, psychiatric hospitals, and CAHs by adding a new standard, ''Electronic Notifications,'' that would require hospitals, psychiatric hospitals, and CAHs to send electronic patient event notifications of a patient's admission, discharge, and/or transfer to another health care facility or to another community provider. We propose to limit this requirement to only those hospitals, psychiatric hospitals, and CAHs which currently possess EHR systems with the technical capacity to generate information for electronic patient event notifications, recognizing that not all Medicare- and Medicaid-participating hospitals and psychiatric hospitals have been eligible for past programs promoting adoption of EHR systems. We intend for these notifications to be required, at minimum, for inpatients admitted to, and discharged and/or transferred from the hospital, psychiatric hospital, or CAH. These requirements would help support coordination of a patient's care between settings or with services received through different care settings. These sections would require updates to discharge planning processes, which has been a long-standing industry practice. Electronic patient event notifications from these care settings, or clinical event notifications, are one type of health information exchange intervention that has been increasingly recognized as an effective and scalable tool for improving care coordination across settings. These notifications are typically automated, electronic communications from the admitting or discharging provider to a receiving facility or to another community provider that alert the receiving provider that a patient is receiving, or has received, care at a different setting.

These notifications are based on ''admission, discharge, and transfer'' (ADT) messages, a standard message used within an EHR as the vehicle for communicating information about key changes in a patient's status as they are tracked by the system (more information about the current standard supporting these messages is available at *http://www.hl7.org/implement/standards/product_brief.cfm?product_id=144*). As noted in the ISA published by ONC, this messaging standard has been widely adopted across the health care system (see *https://www.healthit.gov/isa/sending-a-notification-a-patients-admission-discharge-andor-transfer-status-other-providers*).

We note that hospitals have an existing responsibility under the CoPs at 42 CFR 482.43(d) to transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care. We wish to emphasize that the proposal in this proposed rule around patient event notifications is independent of the requirement regarding necessary medical information at 42 CFR 482.43(d). As these processes are already required, and as many EHR systems already have an electronic notification system in place, we do not anticipate a significant increase in burden on hospitals, psychiatric hospitals, and CAHs with the adoption of this proposal. However, we recognize that processes to implement this proposal, if finalized, might intersect with the hospital's discharge planning process. We note that nothing in this proposal would affect the hospital's responsibilities under 42 CFR 482.43(d). However, if this proposal is finalized, hospitals might wish to consider ways to fulfill these requirements in ways that reduce redundancy while still fully meeting the provisions of each. For instance, where appropriate, hospitals might seek to include required necessary medical information within the same message as a patient event notification.

XV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XVI. Regulatory Impact Analysis

A. Statement of Need

As described in detail in section III. of this proposed rule, the changes to 42 CFR parts 422, 431, 438, 457 and 45 CFR part 156 are part of the agency's broader efforts to empower patients by ensuring that they have full access to their own health care data, through common technologies and without special effort, while keeping that information safe and secure. Interoperability and the capability for health information systems and software applications to communicate, exchange, and interpret data in a usable and readable format, such as pdf or text, is vital, but allowing access to health care data through pdf and text format also limits the utility and sharing of the data. Moving to a system in which patients have access of their health care data will help empower them to make informed decisions about their health care, as well as share their data with providers who can assist these patients with their health care. Our proposals here are designed to move the Medicare, MA, Medicaid, CHIP and QHP programs further to that ultimate goal of empowering their enrollees. As technology has advanced, we have encouraged states, health plans, and providers to adopt various forms of technology to improve the accurate and timely exchange of standardized health care information; these proposals would enable beneficiaries and enrollees to be active partners in the exchange of electronic health care data by easily monitoring or sharing their data.

States and CMS routinely exchange data on who is enrolled in Medicare, and which parties are liable for paying that beneficiary's Parts A and B premiums. These ''buy-in'' data exchanges support state, CMS, and SSA premium accounting, collections, and enrollment functions. We have become increasingly concerned about the limitations of monthly buy-in data exchanges with states. The relatively long lag in updating buy-in data means that the state is not able to terminate or activate buy-in coverage sooner, so the state or beneficiary may be paying premiums for longer than appropriate. We note that once the data catch up, states and CMS reconcile the premiums by recouping and re-billing, so premiums collected are ultimately accurate, but only with—an administratively burdensome process involving debits and payments between the beneficiary, state, CMS, SSA, and potentially providers. Daily buy-in data exchange would reduce this administrative burden. As described in detail in section VII. of this proposed rule, the changes to 42 CFR parts 406, 407, and 423 establish frequency requirements that necessitate all states to participate in daily exchange of buy-in data, and updates frequency requirements to require all states to participate in daily exchange of MMA file data, with CMS by April 1, 2022.

States submit data on files at least monthly to CMS to identify all dually eligible individuals, including full-benefit and partial-benefit dually eligible beneficiaries (that is, those who get Medicaid help with Medicare premiums, and often for cost-sharing). The MMA file was originally developed to meet the need to timely identify dually eligible beneficiaries for the then-

new Medicare Part D prescription drug benefit. Over time, we used these files' data on dual eligibility status to support Part C capitation risk-adjustment, and most recently, feeding dual eligibility status to Part A and B eligibility and claims processing systems so providers, suppliers, and beneficiaries have accurate information on beneficiary cost-sharing obligations. As CMS now utilizes MMA data on dual eligibility status in systems supporting all four parts of the Medicare program, it is becoming even more essential that dual eligibility status is accurate and up-to-date. Dual eligibility status can change at any time in a month. Waiting up to a month for status updates can negatively impact access to the correct level of benefit at the correct level of payment.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that to the best of our ability presents the costs and benefits of the rulemaking. Table 3 summarizes the estimated costs presented in the Collection of Information section of this proposed rule. We note that estimates below do not account for enrollment growth or higher costs associated with medical care. This is because the cost of requirements to implement patient access through APIs and for states to comply with data exchange requirements are not impacted by enrollment growth or higher costs associated with medical care. Per OMB guidelines, the projected estimates for future years do not take into account ordinary inflation.

TABLE 3—ESTIMATED AGGREGATE COSTS TO THE HEALTH CARE SECTOR BY PROVISION

[CYs 2020 through 2024]

Provision	Regulation section(s)	Calendar year ($ in millions)					Total CY 2020–2024 ($ in millions) *
		2020	2021	2022	2023	2024	
Requirements to Patient Access Through APIs.	§ 422.119, § 431.60, § 438.242, § 457.730, § 457.1233, § 156.221.	275.4	54.7	54.7	54.7	54.7	494.0
Dual Eligible Care Coordination.	§ 406.26, § 407.40, § 423.910.	0.7	2.2	2.2	1.2	0	6.3
Total Cost	.....	276.1	56.9	56.9	55.9	54.7	500.3

* Total may not equal sum of parts due to rounding.

Allocation of Cost Impact by Program: As stated in the Collection of Information Section of this proposed rule, cost estimates have been aggregated at the parent organization level because we believe that an organization that offers commercial, Medicare, Medicaid, and CHIP products would create one system that would be used by all ''plans'' it offers. We note that due to the implementation of APIs across multiple business lines, there is no straightforward method to immediately estimate Parent Organization expenditures on how much of the cost is born by each program.

Preliminary Estimates: Later in this RIA section, we provide several detailed estimates of cost by program where we account for Federal matching for Medicaid and payments by the Trust Fund for Medicare Advantage Organizations. However, these estimates are approximate as explained in detail below. Therefore, the purpose of this preliminary estimate section, is to observe that the costs of this proposed rule are negligible relative to the costs of the various programs it impacts.

For purposes of clarification we use the metric of ''costs per enrollee.'' The ''costs per enrollee'' whether for Medicaid or Medicare, does not refer to actual costs paid by the enrollee but rather is a metric, it is the quotient of total program expenditures divided by total enrollees. The cost per enrollee metric facilitates comparison of costs. Since program expenditures for both Medicaid and MA are typically

hundreds of millions (or billions) of dollars, concepts like negligibility do not have intuitive meaning. Contrastively, the costs per enrollee are more manageable and understandable. The 2018 Medicare Trust Fund [60] states that costs per enrollee are projected to be roughly $12,000–$14,000 for contract years 2020–2023 (Table IV.C3). The costs per enrollee for the Medicaid program are similarly several thousand dollars. We estimate 169 million enrollees will be affected by these provisions since. Currently there are 76, 66,[61] 20,[62] and 7[2] million enrollees in the commercial, Medicaid, MA and separate CHIP programs respectively.

The total first year (implementation) cost per enrollee is $1.63 ($276.1 million cost (Table 3) divided by 169 million enrollees); maintenance cost per enrollee in the following years are 34 cents ($56.9 million total cost (Table 3) divided by 169 million enrollees). The assertion that $1.63 and $0.34 is negligible compared to the $12,000–$14,000 cost per enrollee for the MA program or the several thousand-dollar cost per enrollee for the Medicaid program has intuitive appeal. However, these are very rough preliminary estimates. In the remainder of this RIA, we provide, subject to the limitations noted, more detailed impact by program.

Data Sources for Cost by Program: To obtain allocation of cost by program we used the CMS public use files for MLR data, for 2016.[63] [64] The MLR data sets are for private insurance plans but the issuers of that private (commercial) insurance in many cases also have contracts to provide MA, Medicaid and CHIP managed care plans and report revenue, expense, and enrollment data for these plans on the commercial MLR reporting form.

Thus, these MLR data sets omit organizations that only have Medicare or Medicaid. The data from the CMS MLR files also omits: (1) The CHIP program; and (2) Medicaid State Agencies. We now discuss these omissions to assess the accuracy of using these MLR files.

CHIP: 85 percent of the 194 CHIP managed care plans also offer Medicaid and hence are covered by the parent entity. We believe it reasonable that the remaining CHIP plans also have commercial offerings since it would be inefficient to operate a CHIP-only plan as the total national CHIP enrollment is currently only about 7 million. Similarly, except for one state, CHIP programs are run through the state Medicaid agency; again, there would be one interoperability cost for the one state agency since the resulting software would be used both by Medicaid and CHIP. Thus, while we are leaving out CHIP programs in this analysis since they are not in the CMS MLR files, we do not believe this materially alters the overall picture.

Medicare Advantage: We compared the CMS MLR files with the CMS Trustee Report.[65] According to the Trustee Report (Table IV.C2), total MA revenue for 2016 was $189.1 billion. Thus, the reported amount in the CMS MLR files of $157 billion for MA represents 83 percent (157/189.1) of all MA activity reflected in the Trustee Report. Therefore, we believe the proportions obtained from these MLR files are accurate.

Medicaid: For the year for which these MLR files provide data, 2016, about 70 percent of Medicaid enrollees were enrolled in Medicaid Managed Care.[66] Thus although the MLR files omit State Agencies, we believe that the 70 percent Medicaid enrollees enrolled in Medicaid Managed Care provides a good approximation.

Finally, as noted in the section ''Preliminary Estimates'', independent of these omissions, the average cost per enrollee is capped at $1.63 and $0.34 in first and follow up years.

Best Estimates of Impact per Program: We present two methods to obtain an estimate of cost by program both for purposes of assessing impact on small entities, as well as for purposes of assessing impacts of the provision on the Federal government, programs, and enrollees: We could assume costs proportional to current enrollment, or alternatively, we could assume costs proportional to total premium. For purposes of analyzing impact on small entities and impacts of the provision on the Federal Government, programs, and enrollees we are using the method of assuming costs proportional to total premium (the method of assuming costs proportional to current enrollment will be used below to assess impact on transfers to enrollees).

Among issuers with products in both Commercial and MA or Commercial and Medicaid, the 2016 CMS MLR files show $370 billion reported in premium for commercial plans, $157 billion reported for MA, and $113 billion reported for Medicaid. Consequently, the proportion of interoperability cost for each of the programs is 57.81 percent (370/(370+157+113)), 24.53 percent (157/(370+157+113)), and 17.66 percent (113/(370+157+113)) for Commercial, MA, and Medicaid respectively.

Using these proportions, Table 4 breaks out the top row in Table 3, the total cost by year of implementing and maintaining the API, by program.

TABLE 4—API COSTS (IN MILLIONS) BY YEAR AND PROGRAM

Year	2020	2021	2022	2023	2024	Total
Full Implementation and Maintenance costs (Table 3, Row 1)	275.4	54.7	54.7	54.7	54.7	494.0
Commercial Programs (57.81%)	159.2	31.6	31.6	31.6	31.6	285.6
Medicaid and CHIP programs (17.66%)	48.6	9.7	9.7	9.7	9.7	87.2
Medicare Advantage Programs (24.53%)	67.6	13.4	13.4	13.4	13.4	121.2

[60] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.*

[61] *https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html.*

[62] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report-Items/Contract-Summary-2018-08.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending.*

[63] *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[64] Although the 2017 MLR data recently became available, using them would not change the bottom line of the analysis. The 2016 data gives $113 billion, $157 billion and $370 billion enrollees for commercial, MA, and Medicaid plans respectively resulting in revenue proportions of 57.81 percent, 24.53 percent, 17.68 percent. The 2017 data gives $119.5, $170.3 and $381.5 billion for commercial MA, and Medicaid plans resulting in proportions of 56.8 percent, 25.36 percent, and 17.79 percent. The 76 million commercial enrollees from the 2016 data decreased to 73.5 million in 2017. Using these alternate proportions and numbers would not change significantly our dollar-per-enrollee estimates of impacts.

[65] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf Table IV.C2.*

[66] *https://www.cms.gov/newsroom/press-releases/cms-proposes-changes-streamline-and-strengthen-medicaid-and-chip-managed-care-regulations.*

Methods of Bearing Cost by Program: Commercial plans have the options to deal with increased costs by either temporarily absorbing them (for purposes of market competitiveness), increasing premiums to enrollees, or reducing benefits.

To the extent that issuers increase premiums for plans in the FFE, there would be Federal premium tax credit (PTC) impacts. However, the PTC formula is highly individual-specific, that is, it is the result of the relationship between the premium of the second lowest-cost silver plan applicable to a specific consumer in a specific month, the cost of the actual plan purchased by that consumer for that month, and that consumer's income. Consequently, it would not be possible to estimate the magnitude of the PTC impact with a reliable degree of accuracy, since we cannot predict: (1) What proportion of costs would be passed on to enrollees as increased premiums; (2) to what extent commercial issuers may recoup investment costs through raising premiums on the second-lowest cost silver plans or on other plans; and (3) whether or in what ways such premium increases may impact the PTC calculation or eligibility with respect to various consumers,

To deal with this uncertainty, we list the possible Federal PTC impacts as a qualitative impact. Most importantly, we assume the unlikely worst case scenario that all cost is passed on as premium to the enrollee without subsidization; we then show that the net impact per enrollee per month is extremely small (see Table 7).

Medicare Advantage: Medicare Advantage Organizations (MAOs) pass increased costs back to the Trust Fund. For those (most) MAOs whose bid amount is below the benchmark, the Trust Fund provides total expenditures to the MAOs consisting of: (1) Full payment of the bid amount; and (2) the rebate, a portion of the difference between the benchmark and the bid amount. Since MAOs are increasing their bid amounts to reflect the costs of this proposed rule, it follows that the rebate, equaling the difference between the benchmark and bid, is decreased, resulting in less rebates paid to the MAOs. Based on our historical and projected experience, the rebate is estimated as 34 percent of the difference between benchmark and bid. Thus, although the Trust Fund pays the bid in full, nevertheless, 66 percent of the increased bid costs arising from this proposed rule, are reduced from the rebates. The MAO in its submitted bid, can address this reduction of rebates by either: (1) Temporarily, for marketing purposes, absorbing the loss, and reducing its profit margin; (2) reduce the additional benefits it provides the enrollee paid for by the rebate; or (3) raise enrollee premiums.

Medicaid: State Medicaid agencies may be allowed to allocate the costs of state information retrieval systems between the costs attributable to design, development, installation, or enhancement of the system—at a 90 percent federal match—and for ongoing operations of the system—at a 75 percent federal match.

For Medicaid Managed Care entities, we assume an MCO, PIHP, and PAHP cost for implementing the open API provisions would be built into the capitation rates and matched at the State's medical assistance match rate. For purposes of these estimates we use the weighted FMAP, 58.44.

CHIP: Most states operate Medicaid and CHIP from the same state agency. One state is a notable exception in that it has a separate Medicaid and CHIP agency. The federal government pays an enhanced federal medical assistance percentage (EFMAP) to states for all costs associated with CHIP, including systems costs (this is unlike Medicaid where there are different FMAPs for different types of costs). For federal FY 2019 the EFMAPs will range from 88 to 100 percent. For federal FY 2020 the EFMAPs will range from approximately 76.5 to 93 percent. After federal FY 2020, the EFMAPs will range from approximately 65 to 81.5 percent. Since the CHIP program Federal rebate ranges include the 90 percent and 75 percent federal matching proportions of the Medicaid program, we are applying the 90 percent and 75 percent from Medicaid to the CHIP programs. Since the CHIP program is small relative to the Medicaid program, we believe this approach reasonable.

Table 5 uses these proportions to estimate the impact of the API on the Federal Government. For example, the $28.4 million cost to the Federal government for Medicaid/CHIP for 2020, the implementation year of the API, is obtained by multiplying the State Agency Medical Assistance average match rate to Medicaid Managed Care Plans, 58.44%, by the $48.6 million total cost to Medicaid for 2020 listed in Table 4.

TABLE 5—COSTS (IN MILLIONS) INCURRED BY FEDERAL GOVERNMENT BY PROGRAM AND YEAR

Year	2020	2021	2022	2023	2024	Total
For Commercial Programs	0.0	0.0	0.0	0.0	0.0	0.0
For Medicaid/CHIP programs (58.44%, average State Agency medical assistance match rate)	28.4	5.6	5.6	5.6	5.6	51.0
For Medicare/Advantage Programs (The bid increase in spending due to this proposed rule reduces the difference between the benchmark and the bid. The Trust Fund incurs 34% of this reduction while plans incur 66% of this reduction in the form of smaller rebates than would have been received had the cost of this provision not been included in the bid)	23.0	4.6	4.6	4.6	4.6	41.2

By taking the difference between the respective cells in Tables 4 and 5 we obtain the remaining costs for the API. To this amount must be added the coordination cost for the dual eligibles (row 2 of Table 3). For example, Medicaid/CHIP has a remaining cost of $20.3 million ($48.6 million total cost for 2020 (Table 4) − $28.4 million matched by Medicaid State Agencies (Table 5) + $0.7 million total cost for coordination of dual eligibles (Table 3) * 17.66 percent (proportion of total costs incurred by Medicaid/CHIP (Table 4)). (There are minor differences due to

rounding). The results are summarized in Table 6.

TABLE 6—REMAINING COSTS (IN MILLIONS) FOR API BY YEAR AND PROGRAM

	2020	2021	2022	2023	2024	Total
Commercial	159.6	32.9	32.9	32.3	31.6	289.2
Medicaid/Chip	20.3	4.4	4.4	4.2	4.0	37.4
Medicare Advantage	44.8	9.4	9.4	9.1	8.8	81.5

The further discussion of bearing these costs, is clarified, if we reformulate the costs in terms of costs per enrollee. To do this we use enrollments by program. For commercial enrollment we use the 2016 MLR data, for MA enrollment we use the August 2018 data, and for Medicaid and CHIP we use September 2018 data. These enrollment numbers are 76, 66,[67] 20,[68] and 7[4] million enrollees in the commercial, Medicaid, MA and separate CHIP programs respectively. Thus, for purposes of this analysis, we use a total of 169 million (76+67+20+6) enrollees in all programs. Table 7 presents cost per enrollee by program and year. For example, there is a 28-cent cost to Medicaid/CHIP state agencies in 2020 (20.3 million remaining cost (Table 6) divided by 73 million (66 million Medicaid + 7 million CHIP)).[69]

TABLE 7—COST PER ENROLLEE PER YEAR (DOLLARS AND CENTS) BY PROGRAM

	Current enrollment (millions) by program	2020	2021	2022	2023	2024	Total
Commercial	76	2.10	0.43	0.43	0.42	0.42	3.81
Medicaid/Chip	73	0.28	0.06	0.06	0.06	0.05	0.51
Medicare Advantage	20	2.24	0.47	0.47	0.46	0.44	4.08

Using Table 7 we can assess the approximate impact of the remaining cost.

Commercial: As pointed out above, the Commercial program has the options of absorbing costs or passing costs to enrollees either in the form of premiums or reduced benefits. The cost per enrollee in 2021 through 2024 is under a half dollar and could comfortably be passed on to enrollees. For purposes of market competitiveness, it is very likely that some of the 2020 cost of $2.10 per enrollee will be absorbed by each QHP in an FFE.

Medicaid: Medicaid state agencies are adding a cost under 30 cents per enrollee for 2020–2024. Since total costs per enrollee for the Medicaid program are several thousand dollars we do not believe this additional 30 cents per enrollee cost to be a significant burden.

Medicare Advantage: Medicare Advantage plans in their June-submitted bids would address the reduced rebates (arising from increased bid costs due to the increased costs of this proposed rule being included in the bid) by either: (1) Temporarily absorbing costs by reducing profit margins; (2) reducing additional benefits paid for by the rebates; or (3) raising enrollee cost sharing (however, many plans for competitive reasons would choose to remain zero premium and either absorb losses for one year or reduce additional, rebate-funded benefits in the amount per enrollee shown in Table 7).

Table 8 summarizes these methods of bearing the remaining costs.

TABLE 8—HOW PROGRAMS WOULD DEFRAY REMAINING COSTS

Commercial	Commercial plans have the options of absorbing costs (for example, in 2020 for reasons of market competitiveness), increasing premiums to enrollees, or reducing benefits.
Medicaid/CHIP	Medicaid Managed Care plan would bear the cost (under a dime per enrollee) which is negligible compared to current costs per enrollee.
Medicare Advantage (MA)	MA plans in their June-submitted bids would address the reduced rebates (arising from increased bid costs due to the increased costs of this proposed rule being included in the bid) by either: (1) Temporarily absorbing costs by reducing profit margins; (2) reducing additional benefits paid for by the rebates; or (3) raising enrollee cost sharing (however, many plans for competitive reasons would chose to remain zero premium and either absorb losses for one year or reduce additional, rebate-funded benefits in the amount per enrollee shown in Table 8).

[67] *https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html.*

[68] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report-Items/Contract-Summary-2018-08.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending.*

[69] To give an idea of how the per enrollee per year numbers would change had we used updated enrollment, we note that the latest MA enrollment (as of January 2019) is for January 2019 and is 22 million, the latest Medicaid enrollment is for Oct 2018 and is still 73 million, and the latest commercial enrollment is for 2017 and is 73.5. The resulting per-enrollee-per-year cost impacts would be $2.17, 0.28, and $2.04 versus the numbers in Table 7 which are $2.10, 0.28, and $2.24. These changes per enrollee per year would not affect any of our conclusions about negligibility relative to the 4 and 5 digit per enrollee per year expenses for Medicare, Medicaid and the Federally Funded exchange.

C. Anticipated Effects

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This proposed rule affects (1) Commercial Issuers (2) MA plans, including those that are also Part D sponsors of MA–PD plans, as well as (3) Medicaid MCOs with a minimum threshold for small business size of $38.5 million (*https://www.sba.gov/federal-contracting/contracting-guide/size-standards*).

Assessment of impact is complicated by the fact that costs have been aggregated at the Parent Organization level. A typical Parent Organization might have products with the commercial, MA, or Medicaid/CHIP programs. We have no way of directly assessing the size of Parent Organizations. Therefore, as a proxy, we analyze each program separately.

Medicare Advantage: We first assess the impact on MA plans. To clarify the flow of payments between these entities and the federal government, we note that MAOs submit proposed plan designs and estimates of the amount of revenue necessary to cover the cost of those plan designs (called bids) by the first Monday in June of the year preceding the coverage year. Regulations governing this process are in 42 CFR part 422, subpart F. These bids must be broken down in the following:

(1) The revenue requirements for providing Medicare Part A and Part B benefits with actuarially equivalent cost sharing (this is the ''basic benefit bid'');

(2) The revenue requirements for providing supplemental benefits; and

(3) A Part D bid consistent with Part D regulations in 42 CFR part 423.

These bids project payments to hospitals, providers and staff, as well as the cost of administration and profits. Because the API requirements proposed in this rule will apply to every MA plan and each MA plan must furnish at least the Medicare Part A and Part B benefits, the cost of the API will be built into the administrative component of the basic benefit bid. These bids in turn determine one component of the payments of the Medicare Trust Fund to the MAOs who reimburse providers and other stakeholders for their services. A second component of the Trust Fund payment to MAOs are the rebates, which are a portion of the difference between the basic benefit bid compared to an administratively-set benchmark for the MA plan's service area (currently, based on our past and projected experience, rebates are approximately 66 percent). Benchmarks are based on a formula using an estimate of the Medicare FFE per capita cost for the geographic area, which are adjusted to reflect the per capita cost of each county in the United States and its territories. Payments from the Medicare Trust Funds for monthly capitation are capped at the benchmark; for basic benefit bids under the benchmark, a portion, currently 66 percent, of the difference between the bid and benchmark is made available to the MA organization to either: (1) Pay the premium for supplemental benefits; (2) include reductions in cost sharing; (3) provide additional non-Medicare covered benefits; or (4) provide buy-downs of Part B or Part D premiums. Basic benefit bids that are at or above the benchmark receive payment from the Trust Funds of the benchmark amount, with any excess charged to the enrollee as a premium.

MAOs are made aware of the benchmark through the annual CMS publication, ''Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,'' which, consistent with section 1853 of the Act, is released prior to MAO submission of bids. Therefore, the bids of most MAOs are below the benchmark and consequently most MAOs receive from the Trust Fund a total expenditure equaling payment for the bid plus the rebate.

Because of these proposed API provisions, MAOs would be raising the June-submitted bid amount to reflect additional costs. While the Trust Fund pays these bid amounts in full, the rebate goes down: That is, since the bid amount goes up, the rebate, equaling the difference between the benchmark and bid, decreases and results in less rebate payment to the MAO. The MAO has several options of dealing with these increased bid costs and reduced rebates: The MAO might decide to: (1) Temporarily absorb the loss by reducing its profit margin (so as to reduce the bid amount and thereby increase the rebates); (2) reduce additional benefits paid to the enrollee from the rebates; or (3) raise enrollee premiums so as to compensate for the reduction of enrollee premium that would have happened if the bid had not been increased (note: For marketing purposes, many plans operate at zero premium, and we do not consider this a likely possibility). In this RIA we have referred to options (2) and (3) reduction of additional benefits and raising of enrollee premiums as ''passing the costs to the enrollee'' the intent being that the ''effect'' of reduced rebates is less additional benefits or higher enrollee premiums than would have happened had the cost of the provisions of this proposed rule not been included in the bid.

There are various types of Medicare health plans, including MA HMOs, POS plans, and PPOs; Demonstration plans; Cost Plans; Prescription Drug Plans (PDP); and Programs of All-Inclusive Care for the Elderly (PACE) organizations. This proposed rule affects MA HMOs, MA POS plans, and MA PPOs but does not affect Cost Plans, Prescription Drug Plans nor PACE organizations.

There are a variety of ways to assess whether MAOs meet the $38.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations and projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MAOs fell below the $38.5 million threshold for small businesses. Additionally, an analysis of 2016 data, the most recent year for which we have actual data on MAO net worth, shows that 33 percent of all MAOs fall below the minimum threshold for small businesses.

Medicaid: We next assess the impact on Medicaid MCOs. The Society of Actuaries (SOA) published ''Medicaid Managed Care Organizations: Considerations in Calculating Margin in Rate Setting'' in 2017.[70] The report provided an MS Excel spreadsheet of Medicaid MCOs using data from 2013–2015. That report noted that ''[n]ot every state requires Medicaid MCOs to submit Annual Statements, so not every MCO is represented. MCOs in California and Arizona are shown with a limited set of metrics, based on what was available and provided by HMA [Health Management Associates].'' Of the 231 MCOs listed in the 2015 worksheet, 196 provided data that are adequate to identify MCOs with annual ''revenue'' less than $38.5 million. (NOTE: Since total revenue is reported at the company level, which includes revenue from non-Medicaid sources, we used ''direct premium written'' in the Medicaid portion of the worksheet as a proxy for annual revenue on the individual plan level.) Of the 196 Medicaid MCOs, only

[70] Society of Actuaries, Medicaid Managed Care Organizations: Considerations in Calculating Margin in Rate Setting. Accessed at *https://www.soa.org/research-reports/2017/medicaid-margins/*, pg. 49.

15 MCOs or 7.7 percent had ''revenue'' less than $38.5 million in 2015.

Commercial: Based on the 2016 CMS MLR data, approximately 85 out of 494, or 17 percent of companies (that either had only commercial business, or had commercial plus Medicare and/or Medicaid business) had total premium revenue of less than $38,500,000. In other words, for MA, Medicaid, and Commercial, a significant number of small plans are affected. The RFA requires us to assess whether the rule has a significant impact on the plans which we do next.

If a proposed rule has a substantial impact on a substantial number of small entities, the proposed rule must discuss steps taken, including alternatives, to minimize burden on small entities. While a significant number (more than 5 percent) of not-for-profit organizations and small businesses are affected by this final rule, the impact is not significant. To assess impact, we use the data in Table 3 of this section which shows that the total raw (not discounted) net effect of this final rule over 5 years is 500 million dollars.

Medicare Advantage: We first assess impact on MA plans. Comparing the 500 million dollar number to the total monetary amounts projected to be needed just for 2018, the most recent year on which we have finalized plan submitted bid data (and which is expected to be less than the need in future years including 2019), we find that that the impact of this proposed rule is significantly below the 3 percent–5 percent threshold for significant impact for MA plans.

Medicaid: We next assess impact on Medicaid Managed Care plans. The total projected capitation payment and premiums for 2019 is projected to be $337.6 billion.[71] Hence, the total cost of this proposed rule over 5 years, $500 million, is significantly below the 3 percent–5 percent threshold for significant impact to Medicaid Managed Care plans.

Commercial: As discussed prior to Table 4, based on data in the public, CMS MLR files, commercial plans had a revenue of at least $370 billion in 2016. We say at least, because this only includes organizations with either: (1) Only commercial; (2) both commercial and MA; or (3) both commercial and Medicaid. Had all organizations been included in the CMS MLR files (including those that only offer MA and/or Medicaid) the amount would be greater than $370 billion. Therefore, the aggregate raw cost of this proposed rule over 5 years, $500 million, is significantly below the 3 percent–5 percent threshold for significant impact to Commercial plans.

We conclude, that although a significant number of small plans in all programs are affected by this rule, this impact is not significant.

Besides the fact that the impact is not significant, we are not concerned that small plans will have a burden in implementing these requirements since as indicated above, without considering any rebates or Federal matching funds, the cost of this provision is $1.63 per enrollee per year in the first implementation year, and $0.34 in the following years for maintenance, these per enrollee costs are negligible when compared to the typical costs per enrollee (several thousand dollars).

Consequently, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities and the requirements of the RFA have been met. Please see our detailed analysis of apportionment of costs per program and plan in Tables 4 through 8 and section XVI.H. of this proposed rule for further details.

In addition, section 1102(b) of the Act requires CMS to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–04, enacted March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that is approximately $150 million. The apportionment of total cost between the MA, Medicaid, Commercial and Chip programs is detailed in both section XVI.B. (Tables 4 through 8) and section XVI.H of this RIA showing that costs for both enrollees and the states are small. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a Federalism implication. Therefore, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. There are currently 288 organizations and 56 states and territories. We assume each organization will have one designated staff member who will read the entire rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $139.14 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/naics5_524114.htm*). Assuming an average reading speed, we estimate that it would take approximately 6 hours for each person to review this proposed rule. For each plan and state that reviews the rule, the estimated cost is $834.84 (6 hours × $139.14). Therefore, we estimate that the total cost of reviewing this regulation is $288,020 ($834.84 × 345 reviewers).

1. Requirements for Patient Access Through APIs

To promote our commitment to interoperability, we are proposing new requirements in section III. of this proposed rule for MA organizations at 42 CFR 422.119, Medicaid FFS at 42 CFR 431.60, Medicaid managed care at 42 CFR 438.242, CHIP FFS at 42 CFR 457.730, CHIP managed care at 42 CFR 457.1233, and QHP issuers, excluding SADP issuers, that offer plans through the FFE at 45 CFR 156.221 to implement open APIs for making certain data available to enrollees and the public. These openly published APIs will permit third-party applications to retrieve standardized data for adjudicated claims, encounters with capitated and subcapitated providers, provider remittances, beneficiary cost-sharing, reports of lab test results, provider directories, and preferred drug lists. We believe that these proposals are designed to empower patients by mandating that entities subject to our API proposal take steps—by implementing the API—to enable

[71] Table 17 of Appendix D, ''Capitation Payments and Premiums'', in the CMS report, ''2016 Actuarial Report on the Financial Outlook for Medicaid,'' accessible at URL *https://www.medicaid.gov/medicaid/finance/downloads/medicaid-actuarial-report-2016.pdf.*

enrollees to have access to their data in a usable digital format and have (potentially) easier means to share that data. By making these data readily available and portable to the patient, these initiatives support moving our healthcare system away from a FFS payment system that pays for volume and toward a payment system that pays for value and quality by reducing duplication of services, adding efficiency to provider visits, and facilitating identification of fraud, waste, and abuse.

To estimate the number of impacted issuers, we reviewed parent organizations of health plans across MA, Medicaid MCOs, and QHPs in FFEs to remove organizations that would not be subject to our proposal, such as SADPs; transportation plans and brokers such as non-emergency medical transportation (NEMTs) brokers; PACE; visiting nurse and home health care organizations; senior organizations such as Area Agencies on Aging; and other organizations such as community action programs. After removing these organizations, we then reviewed the remaining names of parent organizations and health plans in the National Association of Insurance Commissioners (NAIC) Consumer Information Support (CIS) system to determine the legal name of the entity and whether the entity was registered with the NAIC. We also used the 2018 NAIC Listing of Companies to determine whether various health plans had associated parent organizations using the NAIC's Group coding and numbering system. If the health plan or parent organization did not appear in the NAIC CIS or in the 2018 NAIC Listing of Companies, we then reviewed the name of the entity in the Securities and Exchange online Edgar system to locate the entity's Form 10–K filing, which includes an Exhibit (Exhibit 21) that requires the entity to list its subsidiaries. If the health plan or organization did not appear in these online systems or listings, an online internet search using Google search engine was conducted. After review, we have determined that 288 issuers and 56 states, territories, and U.S. commonwealths, which operate FFS programs, will be subject to the API provisions for Medicare, Medicaid, and the Commercial market. To this we add the one state that operates its CHIP and Medicaid separately. Thus, we have a total of 345 parent entities (288+56+1). We note that although 42 states have some lower-income children in an expansion of Medicaid, and some higher-income children or pregnant women in a separate CHIP, all but one of these programs are operated out of the same agency. Although the CHIP programs may be distinct, we believe they will use the same infrastructure built for Medicaid. Thus, the addition of 1 parent entity for CHIP is reasonable and plausible.

As noted in section XIII.C.3. of this proposed rule, to implement the new requirements for APIs, we estimate that organizations and states would conduct three major work phases: Initial design; development and testing; and long-term support and maintenance. (For a detailed description of these phases, see section XIII.C.3. of this proposed rule.)

As part of our research into the regulatory impact, we reviewed a sample of health plan organizations offering MA plans to determine whether any currently offer patient portal functionality with the MA plan. If yes, we reviewed whether they offered the opportunity to connect to Medicare's Blue Button 2.0. Health plan organizations offering MA plans were identified from June 2018 data and statistics compiled at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html.* We initially reviewed the functionality offered by three organizations which together enroll over half of MA members through review of publicly-available information such as press releases and website informational materials. We found from this review that these organizations not only offered patient portals primarily focused on claims and user-entered data on their website, but that all three also offered enrollees the opportunity to connect to Blue Button. We then identified a selection of other health plan organizations at random and conducted the same evaluation. Results indicate that the majority of the health plan organizations we reviewed offer patients a way to access claims data and other information via their websites and sometimes via applications. Regarding Blue Button access, results were either negative or unclear.

We also cross-referenced health plan organizations offering MA plans with health plan organizations that offer plans in the Federal Employee Health Benefit (FEHB) program because a percentage of those organizations offer plans with patient portal access and Blue Button functionality. The FEHB, administered by the Office of Personnel Management (OPM), reported in 2014 that 90 percent of its participating plans offered enrollees access to a personal health record on the organization's website. In addition, OPM reported that over half of the FEHB participating plans expected to offer Blue Button functionality by January 1, 2016. We sought to learn whether there was any overlap between these two lists of organizations to gauge whether additional organizations may already have the capability to offer either patient portals or Blue Button, albeit in a different business arm, as having internal capability may assuage some of the cost of building out a new API to support patient access to claims data. While we found significant overlap between UnitedHealthcare and the Blue Cross Blue Shield Affiliates, we also were able to identify other organizations that offer both MA plans and plans included in the FEHB. While not definitive, this data allows us to draw the conclusion that a number of health plan organizations have the technology in place to offer patient portals to MA enrollees and, further, also have the ability to offer MA enrollees Blue Button functionality.

As detailed in the Collection of Information section of this proposed rule and summarized in Table 3, given the current state of interoperability, we estimate the burden related to the new requirements for APIs to have an initial set one-time costs of $798,356 per implementation or an aggregate cost of $275,432,820 ($798,356 × 345 parent entities). For a detailed discussion of the one-time costs associated with implementing the API requirements we refer readers to section XIII.C.3. of this proposed rule. Once the API is established we believe that there will be an annual cost for performing necessary capability and security testing, performing necessary upgrades and vetting of third party applications. We estimate the burden related to the requirements for APIs to have an annual cost of $158,406 per implementation or an aggregate cost of $54,650,070 (345 parent entities × $158,406). For a detailed discussion of the annual costs associated with implementing the API requirements, we refer readers to section XIII.C.3. of this proposed rule.

We are committed to fulfilling our role in promoting interoperability, putting patients first and ensuring they have access to their health care data. We recognize that there are significant opportunities to modernize access to patient data and its ability to share across the health ecosystem. We realize the importance of interoperability and the capability for health information systems and software applications to communicate, exchange, and interpret data in a usable and readable format. Although allowing access to healthcare data through pdf and text format is vital,

it limits the utility of the data, and its ability to be easily accessed and shared. Additionally, we realize that moving to a system in which patients have access to their healthcare data will ultimately empower them to make informed decisions about their healthcare. Our proposals here do not go as far as our goals for how patients will be ultimately empowered but take steps in that direction.

We note that the federal government has spent over $35 billion under the EHR Incentive Programs [72] to incentivize the adoption of EHR systems; however, despite the fact that 78 percent of physicians and 96 percent of hospitals now use an EHR system,[73] progress on system-wide data sharing has been limited. Previous attempts to advance interoperability have made incremental progress but have failed to align the necessary stakeholders to drive momentum in a single direction. Recently, the Administration launched the MyHealthEData initiative.[74] This government-wide initiative aims to empower patients by ensuring that they have full access to their own healthcare data and the ability to decide how their data will be used, while keeping that information safe and secure. MyHealthEData aims to break down the barriers that prevent patients from gaining electronic access to their healthcare data and allow them to access that data from the device or application of their choice that will connect to a plan's API, empowering patients and taking a critical step toward interoperability and patient data exchange.

Health plans should have the ability to exchange data instantly with other payers for care coordination or transitions, and with providers to facilitate more efficient care. Health plans are in a unique position to provide enrollees a complete picture of their claims and encounter data, allowing patients to piece together their own information that might otherwise be lost in disparate systems. We are committed to solving the issue of interoperability and achieving complete patient access in the U.S. health care system and are taking an active approach using all available policy levers and authorities available to move all participants in the health care market toward interoperability and the secure exchange of health care data. The modern internet app economy thrives on an open API software environment. Part of the health care API evolution is incorporating many of the current protocols from leading standards development organizations with the newer Fast Healthcare Interoperability Resources (FHIR) web developer-friendly way of representing clinical data.

2. Increasing the Frequency of Federal-State Data Exchanges for Dually Eligible Individuals

We routinely exchange data with states on who is enrolled in Medicare, and which parties are liable for paying that beneficiary's Part A and B premiums. These buy-in data exchanges support state, CMS, and SSA premium accounting, collections, and enrollment functions. CMS subregulatory guidance, specifically Chapter 3 of the State Buy-in Manual, specifies that states should exchange buy-in data with CMS at least monthly, but provides the option for states to exchange buy-in data with CMS daily or weekly. Likewise, states can choose to receive the CMS response data on a file daily or monthly. Currently, 31 states and the District of Columbia now submit buy-in data to CMS, daily and 28 states and the District of Columbia receive buy-in response files from CMS daily.

We are proposing to establish the frequency requirements in the regulation itself to require all states to participate in daily exchange of buy-in data to CMS, with ''daily'' meaning every business day, but that if no new transactions are available to transmit, data would not need to be submitted on a given business day. We propose that states would be required to begin participating in daily exchange of buy-in data with CMS by April 1, 2022.

We estimate the cost for states to comply with these new requirements to be one-time costs associated with state systems updates, totaling $3,273,965 across impacted states and over the 3-year implementation period. We first identified those states already exchanging data daily, and then determined there are 19 states that we anticipate will need to make a systems change to send buy-in data to CMS daily, and 22 states that we anticipate will need to make a systems change to receive buy-in data from CMS daily. We then estimated that each change would involve 960 hours of computer analyst time at $83.18 per hour, for a one-time cost to be a little less than $80,000 per state, per change. So, a state that needs to make systems updates to both send buy-in data daily, and receive buy-in data daily would have a one-time cost of just under $160,000. We did not estimate any savings related to exchanging buy-in data with greater frequency, as data lags only delay when states are billed for premium costs; delays do not impact the effective date and total costs. While we did not estimate premium savings (since premium collection is ultimately correct), we anticipate that states may experience longer term reduction in administrative burden of making those corrections.

States submit data on MMA files at least monthly to CMS to identify all dually eligible individuals, including full-benefit and partial-benefit dually eligible beneficiaries (that is, those who get Medicaid help with Medicare premiums, and often cost-sharing). While 42 CFR 423.910(d) requires states to submit at least one MMA file each month, states have the option to submit multiple MMA files throughout the month (up to one per day). As CMS now utilizes MMA data on dual eligibility status in systems supporting all four parts of the Medicare program, it is becoming even more essential that dual eligibility status is accurate and up-to-date.

We are proposing to update the frequency requirements in 42 CFR 423.910(d) to require that starting April 1, 2022, all states submit the required MMA file data to CMS daily, and to make conforming edits to 42 CFR 423.910(b)(1). Daily would mean every business day, but that if no new transactions are available to transmit, data would not need to be submitted on a given business day. We estimate the cost for states to comply with these new requirements to be a one-time cost associated with state systems updates, totaling $3,034,406 across impacted states, and across the 3 years which states have to implement the requirement. There are 37 states and the District of Columbia that we anticipate will need to make a systems change to send MMA data to CMS daily. We estimate the one-time cost for a state to be a little less than $80,000 for this MMA data systems change. For a detailed discussion of the costs associated with these requirements we refer readers to section XIII.C. of this proposed rule. We did not estimate any savings related to submitting MMA files daily, as data lags only delay when data are sent; delays do not impact the

[72] May 2018, EHR Incentive Program, Payment Summary Report, accessed at *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May2018_SummaryReport.pdf.*

[73] ONC, *Health IT Dashboard,* ''Office-based Physician Health IT Adoption: State rates of physician EHR adoption, health information exchange & interoperability, and patient engagement (2015),'' *https://dashboard.healthit.gov/apps/physician-health-it-adoption.php* (last accessed July 9, 2018).

[74] *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-03-06.html.*

effective date and total costs. While we did not estimate savings, we anticipate that states may experience longer term reduction in administrative burden.

If these proposals are finalized as proposed, we anticipate that states would have approximately 3 years to implement daily exchange of buy-in and MMA data. For each state there would be a one-time cost to make needed systems changes, and thereafter, no new on-going costs. States will have the ability to choose, in consultation with CMS, when in the 3-year implementation period they want to make this change, with numerous factors impacting in which year they would do so. For the purposes of this impact analysis, we estimated an even distribution beginning in May 2019 and ending in April 2022. The total cost impact over the 3-year implementation period for this provision is $6,308,371 ($3,273,965 + $3,034,406), comprising $0.7 million in FY 2019, $2.2 million in FY 2020, $2.2 million in FY 2021, and $1.2 million in FY 2022. Since the proposed effective date is April 1, 2022, we estimate no costs for FY 2023.

3. Revisions to the Conditions of Participation for Hospitals and Critical Access Hospitals (CAHs)

We are seeking to further expand CMS requirements for interoperability within the hospital and CAH CoPs by focusing on electronic patient event notifications. We are proposing new requirements in section X. of this proposed rule for hospitals at 42 CFR 482.24(d)), for psychiatric hospitals at 42 CFR 482.61(f), and for CAHs at 42 CFR 485.638. Specifically, for hospitals, psychiatric hospitals and CAHs, we are proposing similar requirements to revise the CoPs for Medicare- and Medicaid-participating hospitals, psychiatric hospitals, and CAHs by adding a new standard, ''Electronic Notifications,'' that would require hospitals, psychiatric hospitals, and CAHs to make electronic patient event notifications available to another healthcare facility or to another community provider. We propose to limit this requirement to only those hospitals, psychiatric hospitals, and CAHs which currently possess EHR systems with the technical capacity to generate information for electronic patient event notifications, recognizing that not all Medicare- and Medicaid-participating hospitals have been eligible for past programs promoting adoption of EHR systems. We propose that these notifications would need to be sent at admission and either immediately prior to or at the time of the patient's discharge or transfer to licensed and qualified practitioners, other patient care team members, and PAC services providers and suppliers that: (1) Receive the notification for treatment, care coordination, or quality improvement purposes; (2) have an established care relationship with the patient relevant to his or her care; and (3) for whom the hospital, psychiatric hospital, or CAH has a reasonable certainty of receipt of notifications. As we noted, infrastructure supporting the exchange of electronic health information across settings has matured substantially in recent years. Research studies have increasingly found that health information exchange interventions can effectuate positive outcomes in health care quality and public health outcomes, in addition to more longstanding findings around reductions in utilization and costs. Electronic patient event notifications from hospitals, or clinical event notifications, are one type of health information exchange intervention that has been increasingly recognized as an effective and scalable tool for improving care coordination across settings, especially for patients at discharge. This approach has been identified with a reduction in readmissions following implementation.[75]

These notifications are automated, electronic communications from the provider to another facility or another community provider identified by the patient. These automated communications alert the receiving provider that the patient has received care at a different setting. Information included with these notifications can range from simply conveying the patient's name, basic demographic information, and the sending institution, to a richer set of clinical data depending upon the level of technical implementation. However, regardless of the information included these alerts can help ensure that a receiving provider is aware that the patient has received care elsewhere. The notification triggers a receiving provider to reach out to the patient to deliver appropriate follow-up care in a timely manner. By providing timely notifications, the alert may improve post-discharge transitions and reduce the likelihood of complications resulting from inadequate follow-up care.

Virtually all EHR systems generate the basic messages commonly used to support electronic patient event notifications. We believe that care coordination can have a significant positive impact on the quality of life, consumer experience, and health outcomes for patients. However, we acknowledge that though such activities can have positive impact, they will likely generate some costs. We believe it is difficult to quantify the impact of this proposed change because EHR implementation across care settings varies in maturity rates, leading to potential variance in cost and impact across such settings. We believe that this proposal would impose minimal additional costs on hospitals. The cost of implementing these proposed changes would largely be limited to the one-time cost related initial implementation of the notification system, and to the revision of a policies and procedures as they relate to discharge planning. There also may be some minimal cost associated with communicating these changes to affected staff. However, we believe that these costs would be offset by the benefits derived from positive outcomes in health care quality and public health outcomes. Therefore, while this proposal would impose a minimal burden on hospitals, we believe that, in sum, the changes proposed would greatly benefit patients overall.

4. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model, we are proposing to make various other changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

a. Care Coordination Across Payers

In section V. of this proposed rule, we are proposing a new requirement for MA plans, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs to require these plans to maintain a process to exchange, at a minimum, the USCDI data set upon an enrollee's request. Under our proposal, each of these plans subject to the requirement would, upon an enrollee's request: (1) Accept the data set from another plan that had covered the enrollee within the previous 5 years; (2) send the data set at any time during an enrollee's enrollment and up to 5 years later, to another plan that currently covers the enrollee; and (3) send the data set at any time during enrollment or up to 5 years after

[75] Unruh MA, Jung HY, Kaushal R, Vest JR, Hospitalization event notifications and reductions in readmissions of Medicare FFS beneficiaries in the Bronx, New York. J AM Med Inform Assoc, 2017 Apr 1, accessed at *https://www.ncbi.nlm.nih.gov/pubmed/28395059.*

enrollment has ended to a recipient identified by the enrollee.

Such transactions would be made in compliance with applicable laws.

We believe that sending and receiving this minimum data would help both plan enrollees and health care providers in coordinating care and reducing administrative burden. We believe that this entails utilizing all tools available to us to ensure that plans provide coordinated high-quality care in an efficient and cost-effective way that protects program integrity.

We believe that this proposal would impose minimal additional costs on plans. We note that we do not specify a transport standard in the proposal and anticipate that plans may opt to use APIs, such as the API that this proposed rule would also require. We also anticipate that plans may choose to utilize a regional health information exchange. We believe it is difficult to quantify the impact of this proposed change because plans will likely implement different transport methods, and we cannot predict the selected method plans will choose.

b. Care Coordination Through Trusted Exchange Networks

In section VI. of this proposed rule, we are proposing to require MA plans, Medicaid managed care plans, CHIP managed care entities and QHP issuers in FFEs to participate in trust networks in order to improve interoperability in these programs. We believe that payers and patients' ability to communicate between themselves and with health care providers could considerably improve patient access to data, reduce provider burden, and reduce redundant and unnecessary procedures. A trusted exchange framework allows for the secure exchange of electronic health information with, and use of electronic health information from, other health IT without special effort on the part of the user. Widespread payer participation in such a framework might also allow for more complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law. Under our proposal, participation would be required in a trusted exchange framework that meets the following criteria:

- The trusted exchange network must be able to exchange PHI, defined in 45 CFR 160.103, in compliance with all applicable state and federal laws across jurisdictions.
- The trusted exchange network must connect both inpatient EHRs and ambulatory EHRs.
- The trusted exchange network must support secure messaging or electronic querying by and between patients, providers and payers.

We believe that this proposal would impose minimal additional costs on plans.

D. Alternatives Considered

This proposed rule contains a range of proposed and potential future policies. It provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. We carefully considered the alternatives to this proposed rule but concluded that none would adequately and immediately begin to address the critical issue of the lack of patient access and interoperability, or exchange of health care data within the health care system.

The critical policy decision was how broadly or narrowly to classify the standards required to implement interoperability. Overly prescriptive standards may stifle innovation and, in turn, increase costs. On the other side, broad language surrounding standards risked leaving too much open to interpretation and continuing the uncertainty about which standards would be the most practical and cost-effective to implement. We determined it was most appropriate to propose a technical and standards framework that strikes a balance between these two ends of the spectrum, and to establish that we expect the standards framework to expand and mature as interoperability increases.

A second decision was how broadly or narrowly to apply the proposed policies and requirements. For example, alternatives to requiring health plans to provide claims data to patients via an open API could have been altered in a number of ways, such as requiring more or less information to be provided to patients or, simultaneously, to require additional information beyond that already accessible through existing APIs be provided to patients by providers. Ultimately, we opted to continue to consider most matters pertaining to providers in separate RFIs, such as that in the FY 2019 IPPS proposed rule seeking information about program participation conditions and requirements, and to maintain the policies proposed in this rule as policies that will further enhance and secure the foundation of future interoperability, including through inclusion of payers, through care coordination, and through matters of security and identity confirmation.

As we recognize that advancing interoperability is no small or simple matter, we continue to explore alternatives and potential other policies. We have requested comment for consideration in future rulemaking or subregulatory guidance on a number of alternatives related to whether additional policies or requirements, beyond those proposed herein, should be imposed to promote interoperability. For example, the Innovation Center is seeking comment on general principles around promoting interoperability within Innovation Center models for integration into new models as part of the design and testing of innovative payment and service delivery models. Additionally, we are seeking comment on how we may leverage our program authority to provide support to those working on improving patient matching. For example, we are requesting comment on whether CMS should require, in Medicare FFS, the MA program, Medicaid FFS, CHIP FFS, Medicaid managed care programs, CHIP managed care entities, and the FFEs, use of a particular patient matching software solution with a proven success rate of a certain percentage validated by HHS or a 3rd party. We also continue to consider feedback received from RFIs issued in various rules over the course of the past year and to incorporate those suggestions into our strategy.

E. Accounting Statement and Table

In accordance with OMB Circular A–4, Table 9 depicts an accounting statement summarizing the assessment of the benefits, costs, and transfers associated with this regulatory action.

TABLE 9—ACCOUNTING STATEMENT

Category	Primary estimate	Units		
		Year dollars	Discount rate (%)	Period covered
Benefits:				
Qualitative	• API requirements will alleviative the burden for beneficiaries and enrollees to go through separate processes to obtain access to each system, and the need to manually aggregate information that is delivered in various, often non-standardized, formats. • API requirement allows for the administration of a more efficient and effective Medicaid program by taking advantage of commonly used methods of information sharing and data standardization. • API requirements would help to create a healthcare information ecosystem that allows and encourages the healthcare market to tailor products and services to compete for patients, thereby increasing quality, decreasing costs, and helping them live better, healthier lives.			
Costs:				
Annualized Monetized $ millions/year	106.26	2020	7	2020–2024
	102.73	2020	3	2020–2024

The preceding discussion was an actual cost impact (not a transfer) since goods and computer services are being paid for. Plans have the option of transferring their expenses to enrollees. In practice, because of market competitive forces a plan may decide to operate at a (partial) loss and not transfer the entire cost. It is important to estimate the maximum the transfer could be. Some costs are transferred to the States (for Medicaid and CHIP) and ultimately to the federal government (for Medicare, Medicaid, and CHIP), mitigating the amount transferred to enrollees. One approach to estimate impact on enrollees was made in section XVI.B. of this RIA. However, this analysis did not take into account transfers.

We now re-estimate the potential full transfer. As noted in section Tables 4 through 8 of XVI.B. of this RIA, we have in 2021 through 2024 under a dollar increase in premium as the worst case scenario, and we used actual costs per year. In this alternate analysis we use actual amounts for each of 2021 through 2024 with the initial 1-year cost amortized over 5 years. In other words, we assume a cost of $110 (275.4/5 + 54.7)

We point out that this premium increase should be counterbalanced by projected savings arising from the provisions in this proposed rule. More specifically, we expect the availability of portable electronic transfer of medical data proposed by this rule to increase prevention of future medical illnesses due to better data accessibility. The savings from avoiding one illness or one cheaper procedure would offset the under one-dollar impact. However, we have no way, at this point, of estimating this aspect of the future savings of the rule.

We present two estimates. First, we estimate using the enrollment figures used in Table 7 of this RIA. Table 7 shows that we have 169 million (76+73+20) in programs that will be spending about $110 million per year. Ignoring Federal subsidies, and assuming that all costs will be passed on to enrollees (which is contrary to our experience), the 169 million enrollees would each incur an extra 65 cents (110/169) a year to achieve the $110 million goal. We next estimate using premium versus enrollment as was done in section XVI.B. of this RIA.

Prior to discussing potential transfers to enrollees, we discuss how this proposed rule may affect commercial enrollees not in the MA, Medicaid, CHIP, or FFE programs. Technically, plans are only required to provide interoperability for enrollees in the MA, Medicaid, CHIP, and FFE programs. However, it is both possible and likely, that a Parent Organization providing interoperability for its FFE and other program enrollees as required, may choose to offer this to commercial enrollees. Consequently, it is possible that to cover the cost of offering interoperability to commercial enrollees outside the MA, Medicaid, CHIP and FFE programs, the Parent Organizations, raise premiums to both their commercial enrollees as well as the MA, Medicaid, CHIP or FFE enrollees. Thus it is possible (and we argue likely) that this proposed rule will affect commercial enrollees even though there is no requirement to provide them interoperability. Therefore, we believe we are obligated in this RIA to calculate the cost impact per enrollee should the Parent Organizations offer interoperability (and should they pass on the cost of interoperability in terms of commercial premium). The rest of the discussion below explores this possibility.[76]

Commercial: Rebates are required under section 2718(b)(1)(A) of the PHSA and the implementing regulations at 45 CFR part 158 when an issuer does not meet the applicable threshold. The

[76] Note that our analysis in Tables 5,6,7,8 also assume that costs are incurred by commercial enrollees even though there is no requirement to provide them with interoperability. We believe this the most likely scenario. However, if we are restrictive in our impact analysis and only assume MA, Medicaid, CHIP and FFE enrollees are bearing the cost the results of Tables 5–8 would not change the negligibility conclusion as the following justifications show: We have assumed 20 million, 73 million and 76 million enrollees in the MA, Medicaid and Commercial programs (Table 7). The 20 million and 73 million remain accurate. The 76 million (commercial enrollees) must be replaced by FFE enrollees. For this purpose we use QHP data. Based on internal data (some of which has not yet been published), for 2017 there were 9,757,747 enrollees with $55,109,210,072 total premium resulting in a $5600 per enrollee per year cost, and for 2018, there were 9,925,382 enrollees with $70,738,585,845 total premium resulting in a $7100 per enrollee per year cost. To illustrate how this changes the Table 7 impact, the $2.10 per enrollee per year cost for 2020 commercial must be replaced by $15.96 to account for a division by 10 million versus 76 million. Although this is a big increase, $15.96 is still only about one third a percent of the per-enrollee-per-year costs of the FFE. Thus the cost is still negligible. Furthermore, a Parent Organization actuary reviewing these numbers would probably seriously recommend that all enrollees including commercial be offered the interoperability since that significantly reduces the per enrollee per year cost.

commercial market MLR is generally calculated as the percent of each dollar of after-tax premium revenue spent by the issuer on medical products and services, and activities that improve the quality of health care. If the issuer MLR for a state market is below the applicable threshold, then the issuer must return the difference to policyholders. It follows, that if interoperability costs raise plan costs, and if additionally, the issuers pass on the full cost in the form of premium and/or are able to treat these costs as QIAs, then premiums and rebates will change. The following two highly simplified examples are illustrative.

Suppose the MLR threshold is 85 percent (in practice it can vary by state market), but the issuer's MLR is below the threshold at 75 percent. Then the issuer would have to return the 10 percent as a rebate. If the interoperability costs for an issuer are on average 6 percent of premium and the issuer treats these expenses as QIA, the issuer will now have to rebate only 4 percent instead of 10 percent (that is, the issuer's MLR would be 81 percent rather than 75 percent). Similarly, if both the applicable threshold and issuer MLR are 85 percent, then the issuer would not owe a rebate.

There are two effects of recognizing these costs as QIA: (1) For issuers below the applicable MLR threshold, the rebate from issuers to policyholders would go down by some amount between $0 and the interoperability cost; and (2) for issuers at or above the MLR standards, the premium transfers from enrollees to issuers will go up by some amount between $0 and the interoperability cost.

To estimate these amounts, we used the public use 2016 MLR files on the CMS website that were used for Tables 4 through 7 of this RIA. The total 2016 premium revenue on the commercial side was approximately $370 billion. Of the $370 billion, the total 2016 premium revenue of issuers that were below the commercial MLR standard (80 or 85 percent, depending on the market) was approximately $19.4 billion and that subset of issuers paid a total of $455 million in rebates.

As mentioned earlier, to proceed further we use the estimates of the interoperability costs which are $110 million per year. This cost is for all parent organizations with each parent organization possibly dealing with up to four lines of business subject to MLR requirements: MA (including Part D sponsors); Medicaid; CHIP; and Commercial. Thus, of the $110 million level annual cost of interoperability, we estimate $64 million (57.81 percent commercial proportion x $110 million level annual interoperability cost) to be the cost for the commercial market.

In estimating the transfers to policyholders in the commercial market, we must distinguish between the $19.4 billion of premium revenues of issuers whose MLR was below the applicable threshold and the $350.6 billion of premium revenues ($370 billion total revenue − $19.4 billion) of issuers whose MLR was at or above the applicable threshold. We can now calculate the estimated aggregate transfer in the commercial market from the policyholders to the issuers whether through premium or rebates as follows:

- Interoperability cost = 0.017 percent of revenue premium ($64 million cost/ $370 billion total revenue).
- Reduced MLR rebates = $3.3 million (0.017 percent × $19.4 billion premium from issuers below the applicable MLR threshold).
- Increased premiums = Up to $60.0 million (0.017 percent × ($370 billion total revenue − $19.4 billion premium from issuers below the applicable MLR threshold)).
- Total transfer from enrollees = Up to $63.3 million ($60.0 million increased premium + $3.3 million reduced rebate).
- Transfer per enrollee = 83 cents ($63.3 million/76 million commercial enrollee).

We note that the 83 cents (under a dollar per enrollee) is consistent with the results obtained in Tables 4 through 8 (with exact raw amounts by year without amortization of a large first year expense). These calculations are summarized in Table 10.

These calculations are summarized in Table 10.

TABLE 10—TRANSFERS TO ENROLLEE RESULTING FROM THE PROPOSED RULE

Level Annual Cost of Interoperability				
(A)	First year cost of interoperability	275.4	Estimated in this proposed rule.	In millions.
(B)	First year cost amortized over 5 years	55.08	(A)/5	In millions.
(C)	Continuation year cost of interoperability	54.7	Estimated in this proposed rule.	In millions.
(D)	Level interoperability cost per year	109.78	(B) + (C)	In millions.
Commercial Percent of Premium Revenues				
(E)	Total premium revenues in commercial, Medicaid and Medicare.	640	Sum of (F) (G) and (H) Below	In billions.
(F)	Commercial Premium revenues (dollar amount and percent).	370	58%	2016 CMS MLR files (in billions); Percentage obtained by dividing by column E.
(G)	Medicare Advantage Premium revenues (Dollar amount and percent).	157	25%	2016 CMS MLR files (in billions); Percentage obtained by dividing by column E.
(H)	Medicaid Premium revenues (Dollar amount and percent).	113	18%	2016 CMS MLR files (in billions); Percentage obtained by dividing by column E.
Annual Interoperability Cost as a Percent of Commercial Premium Revenues				
(I)	Annualized Level interoperability cost	109.78	(D)	In millions.
(J)	Percent of total revenues related to commercial market.	58%	(F)	
(K)	Interoperability cost for commercial issuers	63.67	(I) × (J)	In millions.
(L)	Commercial Premium revenues	370,000	(F)	In millions.

TABLE 10—TRANSFERS TO ENROLLEE RESULTING FROM THE PROPOSED RULE—Continued

(M)	Interoperability cost as a percent of total commercial revenue.	0.017%	(K)/(L)	
Commercial Revenue Broken Out by Whether Above or Below MLR Threshold (Requiring Rebate)				
(N)	Total Commercial Revenue	370,000	(F)	In millions.
(O)	Revenues of commercial market issuers whose MLR is below threshold.	19,400	2016 CMS MLR files (in millions).	
(P)	Revenues of commercial market issuers whose MLR is at or above the threshold.	350,600	(N) − (O)	In millions.
Transfer To Enrollee per Enrollee From Decreased Rebates and Increased Premium				
(Q)	Reduction in commercial market rebates from interoperability for those issuers paying rebates.	3.3	(M) × (O)	In millions.
(R)	Premium increase from interoperability for those commercial market issuers not paying rebates.	60.0	(M) × (P)	In millions.
(S)	Total increase to commercial enrollees from interoperability.	63.3	(Q) + (R)	In millions.
(T)	Number Commercial Enrollees	76	2016 CMS MLR files (in millions).	
(U)	Dollar increase in premium per enrollee	$0.83	(S)/(T)	

F. Regulatory Reform Analysis under E.O. 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule is considered an E.O. 13771 regulatory action. We estimate that this rule generates $56.7 million in annualized costs, discounted at 7 percent relative to year 2016, over an infinite time horizon. Details on the estimated costs of this proposed rule can be found in the preceding analysis.

G. Conclusion

The analysis above, together with the preceding preamble, provides an RIA.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 406

Health facilities, Diseases, Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services (CMS) proposes to amend 42 CFR chapter IV and the Office of the Secretary (HHS) proposes to further amend 45 CFR subtitle A, subchapter B (as proposed to be amended in ONC's proposed rule ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' published elsewhere in this issue of this **Federal Register**), as set forth below:

Title 42—Public Health

Chapter IV—Centers For Medicare & Medicaid Services, Department of Health and Human Services

PART 406—HOSPITAL INSURANCE ELIGIBLIITY AND ENTITLEMENT

■ 1. The authority citation for part 406 is revised to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

■ 2. Section 406.26 is amended by adding paragraph (a)(1)(i) and adding and reserving paragraph (a)(1)(ii) to read as follows:

§ 406.26 Enrollment under State buy-in.

(a) * * *

(1) * * *

(i) Any State that has a buy-in agreement in effect must participate in

daily exchanges of enrollment data with CMS.

(ii) [Reserved]

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

■ 3. The authority citation for part 407 is revised to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

■ 4. Section 407.40 is amended by adding paragraph (c)(4) to read as follows:

§ 407.40 Enrollment under a State buy-in agreement.

* * * * *

(c) * * *

(4) Any State that has a buy-in agreement in effect must participate in daily exchanges of enrollment data with CMS.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 5. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C 1395w26 and 1395w–27.

■ 6. Section 422.119 is added to read as follows:

§ 422.119 Access to and exchange of health data and plan information.

(a) *Application Programming Interface to support MA enrollees.* A Medicare Advantage (MA) organization must implement and maintain an open Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of an individual MA enrollee, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the enrollee.

(b) *Accessible content.* (1) An MA organization must make the following information accessible to its enrollees through the API described in paragraph (a) of this section:

(i) Standardized data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and enrollee cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(ii) Standardized encounter data, no later than one (1) business day after data concerning the encounter is received by the MA organization;

(iii) Provider directory data on the MA organization's network of contracted providers, including names, addresses, phone numbers, and specialties, updated no later than 30 business days after changes are made to the provider directory; and

(iv) Clinical data, including laboratory results, if the MA organization manages any such data, no later than one (1) business day after the data is received by the MA organization.

(2) In addition to the information specified in paragraph (b)(1) of this section, an MA organization that offers an MA–PD plan must make the following information accessible to its enrollees through the API described in paragraph (a) of this section:

(i) Standardized data concerning adjudicated claims for covered Part D drugs, including remittances and enrollee cost-sharing, no later than 1 business day after a claim is adjudicated;

(ii) Pharmacy directory data, including the number, mix, and addresses of network pharmacies; and

(iii) Formulary data that includes covered Part D drugs, and any tiered formulary structure or utilization management procedure which pertains to those drugs.

(c) *Technical requirements.* An MA organization:

(1) Must implement, maintain, and use API technology conformant with 45 CFR 170.215;

(2) Must conduct routine testing and monitoring to ensure the API functions properly, including assessments to verify that the API is fully and successfully implementing privacy and security features such as, but not limited to, those minimally required to comply with HIPAA privacy and security requirements in 45 CFR part 164, 42 CFR parts 2 and 3, and other applicable law protecting the privacy and security of individually identifiable data;

(3) Must comply with the following regulations regarding content and vocabulary standards for data available through the API, where applicable to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such standards are the only available standards for the data type or element;

(ii) Content and vocabulary standards at 45 CFR part 162 and 42 CFR 423.160 where required by law or where such standards are the only available standards for the data type or element; or

(iii) The content and vocabulary standards in either paragraph (c)(3) (i) or (ii) of this section as determined appropriate for the data type or element, where a specific data type or element may be encoded or formatted using content and vocabulary standards in either paragraph (c)(3)(i) or (ii) of this section.

(4) May use an updated version of any standard or all standards required under paragraph (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law, or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or 45 CFR part 170;

(B) For standards at 45 CFR 170.213 and 45 CFR 170.215, the National Coordinator has approved the updated version for use in the ONC Health IT Certification Program; and

(C) Where use of the updated version of a standard does not disrupt an end user's ability to access the data described in paragraph (b) of this section through the API described in paragraph (a) of this section.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, an MA organization must make publicly accessible, by posting directly on its website or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* An MA organization may deny or discontinue any third party application's connection to the API required under paragraph (a) of this section if the MA organization:

(1) Reasonably determines that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of protected health information on the MA organization's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which enrollees seek to access their electronic health information, as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

(f) *Coordination among payers.* (1) MA organizations must maintain a process for the electronic exchange of, at a minimum, the data classes and elements included in the regulations regarding the content standard adopted at 45 CFR 170.213. Such information received by an MA organization must be incorporated into the MA organization's records about the enrollee. At the request of an enrollee, the MA organization must:

(i) Receive such data from any other health care plan that has provided coverage to the enrollee within the preceding 5 years;

(ii) At any time an enrollee is currently enrolled in the MA plan and up to 5 years after disenrollment, send such data to any other health care plan that currently covers the enrollee; and

(iii) At any time the enrollee is currently enrolled in the MA plan and up to 5 years after disenrollment, send such data to a recipient designated by the enrollee.

(2) MA organizations must participate in a trusted exchange network which:

(i) Is capable of exchanging protected health information, defined at 45 CFR 160.103, in compliance with all applicable State and Federal laws across jurisdictions;

(ii) Is capable of connecting to inpatient electronic health records and ambulatory electronic health records; and

(iii) Supports secure messaging or electronic querying by and between providers, payers and patients.

(g) *Enrollee resources regarding privacy and security.* An MA organization must provide on its website and through other appropriate mechanisms through which it ordinarily communicates with current and former enrollees seeking to access their health information held by the MA organization, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application, and understanding the security and privacy practices of any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of OCR and FTC, and how to submit a complaint to:

(i) The HHS Office for Civil Rights; and

(ii) The Federal Trade Commission (FTC).

(h) *Applicability.* This section is applicable beginning on and after January 1, 2020.

■ 7. Section 422.504 is amended by adding paragraph (a)(18) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(18) To comply with the requirements for access to health data and plan information under § 422.119.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 8. The authority citation for part 423 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 9. Section 423.910 is amended—

■ a. In paragraph (b)(1) introductory text by removing the phrase ''monthly reporting requirement for the monthly enrollment reporting'' and adding in its place the phrase ''state enrollment reporting requirement described in paragraph (d) of this section'';

■ b. In paragraph (d) by revising the paragraph heading and by redesignating the text of paragraph (d) introductory text as paragraph (d)(1).

■ c. In newly redesignated paragraph (d)(1), by removing the phrase ''Effective June 2005, and each subsequent month,'', and following the phrase ''in a manner specified by CMS'' by adding the following phrase ''and frequency specified in paragraph (d)(2) of this section,''; and

■ d. By adding paragraph (d)(2).

The addition reads as follows:

§ 423.910 Requirements.

* * * * *

(d) *State enrollment reporting.* * * *

(2)(i) For the period prior to April 1, 2022, States must submit the file at least monthly and may submit updates to that file on a more frequent basis.

(ii) For the period beginning April 1, 2022, States must submit the file at least monthly and must submit updates to that file on a daily basis.

* * * * *

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 10. The authority citation for part 431 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 11. Section 431.60 is added to subpart B to read as follows:

§ 431.60 Beneficiary access to and exchange of data.

(a) *Application Programming Interface to support Medicaid beneficiaries.* A State must implement and maintain an open Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of a beneficiary, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the beneficiary.

(b) *Accessible content.* A State must make the following information accessible to its beneficiaries through the API described in paragraph (a) of this section:

(1) Standardized data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and beneficiary cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(2) Standardized encounter data through the API within one (1) business day of receiving the data from providers, other than MCOs, PIHPs, and PAHPs, compensated on the basis of capitation payments;

(3) Provider directory information specified in section 1902(a)(83) of the Act, no later than 30 calendar days after the State receives provider directory information or updates to provider directory information;

(4) Clinical data, including laboratory results, if the State manages any such data, no later than one (1) business day after the data is received by the State; and

(5) Information about covered outpatient drugs and updates to such information, including, where applicable, preferred drug list information, no later than one (1) business day after the effective date of any such information or updates to such information.

(c) *Technical requirements.* A State:

(1) Must implement, maintain, and use API technology conformant with 45 CFR 170.215;

(2) Must conduct routine testing and monitoring to ensure the API functions properly, including assessments to

verify that the API is fully and successfully implementing privacy and security features such as, but not limited to, those minimally required to comply with HIPAA privacy and security requirements in 45 CFR part 164, 42 CFR parts 2 and 3, and other applicable law protecting the privacy and security of individually identifiable data;

(3) Must comply with the following regulations regarding content and vocabulary standards for data available through the API, where applicable to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such standards are the only available standards for the data type or element;

(ii) Content and vocabulary standards at 45 CFR part 162 and 42 CFR 423.160 where required by law, or where such standards are the only available standards for the data type or element; or

(iii) The content and vocabulary standards in either paragraphs (c)(3)(i) or (ii) of this section, as determined appropriate for the data type or element, where a specific data type or element may be encoded or formatted using content and vocabulary standards in either paragraph (c)(3)(i) or (ii) of this section.

(4) May use an updated version of any standard or all standards required under paragraph (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law, or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or 45 CFR part 170;

(B) For standards at 45 CFR 170.213 and 45 CFR 170.215, the National Coordinator has approved the updated version for use in the ONC Health IT Certification Program; and

(C) Where use of the updated version of a standard does not disrupt an end user's ability to access the data described in paragraph (b) of this section through the API described in paragraph (a) of this section.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, a State must make publicly accessible, by posting directly on its website or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* A State may deny or discontinue any third-party application's connection to the API required under paragraph (a) of this section if the State:

(1) Reasonably determines that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of protected health information on the State's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which beneficiaries seek to access their electronic health information as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

(f) *Beneficiary resources regarding privacy and security.* The State must provide on its website and through other appropriate mechanisms through which it ordinarily communicates with current and former beneficiaries seeking to access their health information held by the State Medicaid agency, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application, and understanding the security and privacy practices of any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of OCR and FTC, and how to submit a complaint to:

(i) The HHS Office for Civil Rights; and

(ii) The Federal Trade Commission (FTC).

(g) *Applicability.* This section is applicable beginning on or after July 1, 2020.

PART 438—MANAGED CARE

■ 12. The authority citation for part 438 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 13. Section 438.62 is amended by adding paragraph (b)(1)(vi) to read as follows:

§ 438.62 Continued services to enrollees.

* * * * *

(b) * * *

(1) * * *

(vi) A process for the electronic exchange of, at a minimum, the data classes and elements included in the regulations regarding the content standard at 45 CFR 170.213. Information received by the MCO, PIHP, or PAHP must be incorporated into the MCO's, PIHP's, or PAHP's records about the enrollee. At the request of an enrollee, the MCO, PIHP, or PAHP must:

(A) Accept such data from any other health care plan that has provided coverage to the enrollee within the preceding 5 years;

(B) At any time the enrollee is currently enrolled in the MCO, PIHP, or PAHP and up to 5 years after disenrollment, send such data to any other health care plan that currently covers the enrollee; and

(C) At any time the enrollee is currently enrolled in the MCO, PIHP, or PAHP and up to 5 years after disenrollment, send such data to any other recipient designated by the enrollee.

* * * * *

■ 14. Section 438.242 is amended by adding paragraphs (b)(5) and (6) to read as follows:

§ 438.242 Health information systems.

* * * * *

(b) * * *

(5) Participate in a trusted exchange network which:

(i) Is capable of exchanging protected health information as defined in 45 CFR 160.103, in compliance with all applicable State and Federal laws from all relevant jurisdictions;

(ii) Is capable of connecting to inpatient electronic health records and ambulatory electronic health records, and;

(iii) Supports secure messaging or electronic querying by and between providers, payers and patients.

(6) Implement an Application Programming Interface (API) as specified in § 431.60 of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP and

(i) Include all standardized encounter data, including encounter data from any network providers the MCO, PIHP, or PAHP is compensating on the basis of capitation payments and adjudicated claims and encounter data from any subcontractors; and

(ii) Provider directory information required in § 431.60(b)(3) of this chapter, which must include all information required in § 438.10(h)(1).

* * * * *

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 15. The authority citation for part 457 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 16. Section 457.700 is amended by—

■ a. Redesignating paragraphs (a)(1) and (2) as paragraphs (a)(2) and (3), respectively;

■ b. Adding paragraph (a)(1);

■ c. Revising paragraph (c).

The addition and revision reads as follows:

§ 457.700 Basis, scope, and applicability.

(a) * * *

(1) Section 2101(a) of the Act, which sets forth that the purpose of title XXI is to provide funds to States to provide child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage;

* * * * *

(c) *Applicability.* The requirements of this subpart apply to separate child health programs and Medicaid expansion programs, except that § 457.730 does not apply to Medicaid expansion programs. Separate child health programs that provide benefits exclusively through managed care organizations may meet the requirements of § 457.730 by requiring the managed care organizations to meet the requirements of § 457.1233(d)(2).

■ 17. Section 457.730 is added to read as follows:

§ 457.730 Beneficiary access to and exchange of data.

(a) *Application Programming Interface to support CHIP beneficiaries.* A State must implement and maintain an open application programming interface (API) that permits third-party applications to retrieve, with the approval and at the direction of the individual beneficiary, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the beneficiary.

(b) *Accessible content.* A State must make the following information accessible to its beneficiaries through the API described in paragraph (a) of this section:

(1) Standardized data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and beneficiary cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(2) Standardized encounter data through the API within one (1) business day of receiving the data from providers, other than MCOs, PIHPs, or PAHPs, compensated on the basis of capitation payments;

(3) Provider directory information, including updated provider information no later than 30 calendar days after the State receives updated provider information;

(4) Clinical data, including laboratory results, if a State manages any such data, no later than one (1) business day after the data is received by the State; and

(5) Information, about covered outpatient drugs and updates to such information, including, where applicable, preferred drug list information, no later than one (1) business day after the effective date of the information or updates to such information.

(c) *Technical requirements.* A State:

(1) Must implement, maintain, and use API technology conformant with 45 CFR 170.215;

(2) Must conduct routine testing and monitoring to ensure the API functions properly, including assessments to verify that the API technology is fully and successfully implementing privacy and security features such as, but not limited to, those minimally required to comply with HIPAA privacy and security requirements in 45 CFR part 164, 42 CFR parts 2 and 3, and other applicable law protecting the privacy and security of individually identifiable data;

(3) Must comply with the following regulations regarding content and vocabulary standards for data available through the API, where applicable to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such standards are the only available standards for the data type or element;

(ii) Content and vocabulary standards at 45 CFR part 162 and 42 CFR 423.160 where required by law, or where such standards are the only available standards for the data type or element; or

(iii) The content and vocabulary standards in either paragraphs (c)(3)(i) or (ii) of this section, as determined appropriate for the data type or element, where a specific data type or element may be encoded or formatted using content and vocabulary standards in either paragraphs (c)(3)(i) or (ii) of this section.

(4) May use an updated version of any standard or all standards required under paragraphs (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law, or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or 45 CFR part 170;

(B) For standards at 45 CFR 170.213 and 45 CFR 170.215, the National Coordinator has approved the updated version for use in the ONC Health IT Certification Program; and

(C) Where use of the updated version of a standard does not disrupt an end user's ability to access the data described in paragraph (b) of this section through the API described in paragraph (a) of this section.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, a State must make publicly accessible, by posting directly on its website or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations that an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* A State may deny or discontinue any third-party application's connection to the API required under paragraph (a) of this section if the State:

(1) Reasonably determines that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of protected health information on the State's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which beneficiaries seek to access their electronic health information as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

(f) *Beneficiary resources regarding privacy and security.* A State must provide on its website and through other appropriate mechanisms through which it ordinarily communicates with current and former beneficiaries seeking to access their health information held by the State CHIP agency, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application, and understanding the security and privacy practices of any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of OCR and FTC, and how to submit a complaint to:

(i) The HHS Office for Civil Rights; and

(ii) The Federal Trade Commission (FTC).

(g) *Applicability.* This section is applicable beginning on or after July 1, 2020.

■ 18. Section 457.1233 is amended by revising paragraph (d) to read as follows:

§ 457.1233 Structure and operations standards.

* * * * *

(d) *Health information systems.* (1) The State must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the health information systems requirements as provided in § 438.242(a), (b)(1) through (5), (c), (d), and (e) of this chapter.

(2) Each MCO, PIHP, and PAHP must implement an Application Programming Interface (API) as specified in § 457.730 as if such requirements applied directly to the MCO, PIHP, or PAHP, and

(i) Include all standardized encounter data, including encounter data from any network providers the MCO, PIHP, or PAHP is compensating on the basis of capitation payments and adjudicated claims and encounter data from any subcontractors; and

(ii) Provider directory information required in § 457.730(b)(3), which must include all information required in § 438.10(h)(1) of this chapter.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION: HOSPITALS

■ 19. The authority citation for part 482 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 20. Sections 482.24 is amended by adding paragraph (d) to read as follows:

§ 482.24 Conditions of participation: Medical record services.

* * * * *

(d) *Standard: Electronic notifications.* If the hospital utilizes an electronic medical records system with the capacity to generate information for patient event notifications in accordance with paragraph (d)(2) of this section, then the hospital must demonstrate that—

(1) The system's notification capacity is fully operational and that it operates in accordance with all State and Federal statutes and regulations regarding the exchange of patient health information;

(2) The system complies with the regulations regarding the content exchange standard at 45 CFR 170.205(a)(4)(i);

(3) The system sends notifications that must include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law, patient diagnosis);

(4) At the time of the patient's admission to the hospital, the system sends notifications directly or through an intermediary that facilitates exchange of health information, to licensed and qualified practitioners, other patient care team members, and post-acute care services providers and suppliers:

(i) That receive the notification for treatment, care coordination, or quality improvement purposes;

(ii) That have an established care relationship with the patient relevant to his or her care; and

(iii) For whom the hospital has a reasonable certainty of receipt of notifications; and

(4) Either immediately prior to or at the time of the patient's discharge or transfer from the hospital, the system sends notifications directly or through an intermediary that facilitates exchange of health information, to licensed and qualified practitioners, other patient care team members, and post-acute care services providers and suppliers:

(i) That receive the notification for treatment, care coordination, or quality improvement purposes;

(ii) That have an established care relationship with the patient relevant to his or her care; and

(iii) For whom the hospital has a reasonable certainty of receipt of notifications.

■ 21. Section 482.61 is amended by adding paragraph (f) to read as follows:

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

* * * * *

(f) *Standard: Electronic notifications.* If the hospital utilizes an electronic medical records system with the capacity to generate information for patient event notifications in accordance with paragraph (f)(2) of this section, then the hospital must demonstrate that—

(1) The system's notification capacity is fully operational and that it operates in accordance with all State and Federal statutes and regulations regarding the exchange of patient health information;

(2) The system complies with the regulations regarding the content exchange standard at 45 CFR 170.205(a)(4)(i);

(3) The system sends notifications that must include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law, patient diagnosis);

(4) At the time of the patient's admission to the hospital, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, to licensed and qualified practitioners, other patient care team members, and post-acute care services providers and suppliers:

(i) That receive the notification for treatment, care coordination, or quality improvement purposes;

(ii) That have an established care relationship with the patient relevant to his or her care; and

(iii) For whom the hospital has a reasonable certainty of receipt of notifications; and

(5) Either immediately prior to or at the time of the patient's discharge or transfer from the hospital, the system sends notifications directly or through an intermediary that facilitates exchange

of health information, to licensed and qualified practitioners, other patient care team members, and post-acute care services providers and suppliers:

(i) That receive the notification for treatment, care coordination, or quality improvement purposes;

(ii) That have an established care relationship with the patient relevant to his or her care; and

(iii) For whom the hospital has a reasonable certainty of receipt of notifications.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 22. The authority citation for part 485 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 23. Section 485.638 is amended by adding paragraph (d) to read as follows:

§ 485.638 Conditions of participation: Clinical records.

* * * * *

(d) *Standard: Electronic notifications.* If the CAH utilizes an electronic medical records system with the capacity to generate information for patient event notifications in accordance with paragraph (d)(2) of this section, then the CAH must demonstrate that—

(1) The system's notification capacity is fully operational and that it operates in accordance with all State and Federal statutes and regulations regarding the exchange of patient health information;

(2) The system complies with the regulations regarding the content exchange standard at 45 CFR 170.205(a)(4)(i);

(3) The system sends notifications that must include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if not prohibited by other applicable law, patient diagnosis);

(4) At the time of the patient's admission to the CAH, the system sends notifications directly or through an intermediary that facilitates exchange of health information, to licensed and qualified practitioners, other patient care team members, and post-acute care services providers and suppliers:

(i) That receive the notification for treatment, care coordination, or quality improvement purposes;

(ii) That have an established care relationship with the patient relevant to his or her care; and

(iii) For whom the CAH has a reasonable certainty of receipt of notifications; and

(5) Either immediately prior to or at the time of the patient's discharge or transfer from the CAH, the system sends notifications directly or through an intermediary that facilitates exchange of health information, to licensed and qualified practitioners, other patient care team members, and post-acute care services providers and suppliers:

(i) That receive the notification for treatment, care coordination, or quality improvement purposes;

(ii) That have an established care relationship with the patient relevant to his or her care; and

(iii) For whom the CAH has a reasonable certainty of receipt of notifications.

TITLE 45—PUBLIC WELFARE

Subtitle A—Department of Health and Human Services

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 24. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701.

■ 25. Section 156.221 is added to read as follows:

§ 156.221 Access to and exchange of health data and plan information.

(a) *Application Programming Interface to support enrollees.* Subject to paragraph (h) of this section, QHP issuers in a Federally-facilitated Exchange, not including stand-alone dental plans (SADP) issuers, must implement and maintain an open Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of an individual enrollee, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the enrollee.

(b) *Accessible content.* (1) A QHP issuer in a Federally-facilitated Exchange must make the following information accessible to its enrollees through the API described in paragraph (a) of this section:

(i) Standardized data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and enrollee cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(ii) Standardized encounter data, no later than one (1) business day after data concerning the encounter is received by the QHP issuer; and

(iii) Clinical data, including laboratory results, if the QHP issuer maintains such data, no later than one (1) business day after data is received by the issuer.

(c) *Technical requirements.* A QHP issuer in a Federally-facilitated Exchange:

(1) Must implement, maintain, and use API technology conformant 45 CFR 170.215;

(2) Must conduct routine testing and monitoring to ensure the API functions properly, including assessments to verify the API is fully and successfully implementing privacy and security features such as, but not limited to, those minimally required to comply with HIPAA privacy and security requirements in 45 CFR part 164, 42 CFR parts 2 and 3, and other applicable law protecting privacy and security of individually identifiable data;

(3) Must comply with the following regulations regarding the content and vocabulary standards for data available through the API where applicable to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such are the only available standards for the data type or element;

(ii) Content and vocabulary standards at 45 CFR part 162 and 42 CFR 423.160 where required by law, or where such standards are the only available standards for the data type or element; or

(iii) The content and vocabulary standards in either paragraph (c)(3)(i) or (ii) of this section as determined appropriate for the data type or element, where a specific data type or element may be encoded or formatted using content and vocabulary standards in either paragraph (c)(3)(i) or (ii) of this section.

(4) May use an updated version of any standard or all standards required under paragraphs (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law, or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or 45 CFR part 170;

(B) For standards at 45 CFR 170.213 and 45 CFR 170.215, the National

Coordinator has approved the updated version for use in the ONC Health IT Certification Program; and

(iii) Where use of the updated version of a standard does not disrupt an end user's ability to access the data described in paragraph (b) of this section through the API described in paragraph (a) of this section.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, a QHP issuer must make publicly accessible, by posting directly on its website and/or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* A QHP issuer in a Federally-facilitated Exchange may deny or discontinue any third party application's connection to the API required under paragraph (a) of this section if the issuer:

(1) Reasonably determines that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of personally identifiable information, including protected health information, on the QHP issuer's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all applications and developers through which enrollees seek to access their electronic health information as defined at 45 CFR 171.102, including but not limited to criteria that may rely on automated monitoring and risk mitigation tools.

(f) *Exchange of data between plans.* (1) Subject to paragraph (d) of this section, QHP issuers in a Federally-facilitated Exchange, not including SADP issuers, must maintain a process for the electronic exchange of, at a minimum, the data classes and elements included in the regulations regarding the content standard at 45 CFR 170.213 of this subchapter. Information received by a QHP issuer must be incorporated into the QHP issuer's records about the enrollee. At the request. A QHP issuer must:

(i) Accept such data from any other health care plan that has provided coverage to the enrollee within the preceding 5 years;

(ii) At any time the enrollee is currently enrolled in the plan and up to 5 years after disenrollment, send such data to any other health care plan that currently covers the enrollee; and

(iii) At any time the enrollee is currently enrolled in the plan and up to 5 years after disenrollment, send such data to a recipient designated by the enrollee.

(2) QHP issuers must participate in a trusted exchange network which:

(i) Is capable of exchanging protected health information, defined at 45 CFR 160.103 of this subchapter, in compliance with all applicable State and Federal laws of relevant jurisdictions;

(ii) Is capable of connecting to inpatient electronic health records and ambulatory electronic health records; and

(iii) Supports secure messaging or electronic querying by and between providers, payers and patients.

(g) *Enrollee resources regarding privacy and security.* A QHP issuer in a Federally-facilitated Exchange must provide on its website and through other appropriate mechanisms through which it ordinarily communicates with current and former enrollees seeking to access their health information held by the QHP issuer, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application, and understanding the security and privacy practices of any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of OCR and FTC, and how to submit a complaint to:

(i) The HHS Office for Civil Rights; and

(ii) The Federal Trade Commission (FTC).

(h) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraphs (a), (b), or (c) of this section, the issuer must include as part of its QHP application a narrative justification describing the reasons why the plan cannot reasonably satisfy the requirements for the applicable plan year, the impact of non-compliance upon enrollees, the current or proposed means of providing health information to enrollees, and solutions and a timeline to achieve compliance with the requirements of this section.

(2) The Federally-facilitated Exchange may grant an exception to the requirements in paragraphs (a), (b), or (c) if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals and qualified employers in the State or States in which such Exchange operates.

(i) *Applicability.* This section is applicable for plan years beginning on or after January 1, 2020.

(ii) [Reserved]

Dated: December 14, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 10, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–02200 Filed 2–22–19; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 84 Monday,

No. 42 March 4, 2019

Part III

Environmental Protection Agency

40 CFR Part 63

National Emission Standards for Hazardous Air Pollutants: Surface Coating of Wood Building Products Residual Risk and Technology Review; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2016–0678; FRL–9988–71–OAR]

RIN 2060–AT71

National Emission Standards for Hazardous Air Pollutants: Surface Coating of Wood Building Products Residual Risk and Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Surface Coating of Wood Building Products source category regulated under national emission standards for hazardous air pollutants (NESHAP). In addition, we are taking final action addressing periods of startup, shutdown, and malfunction (SSM). We are finalizing our proposed determination that the risks are acceptable and that the current NESHAP provides an ample margin of safety to protect public health. We identified no new cost-effective controls under the technology review to achieve further emissions reductions. These final amendments include provisions regarding electronic reporting, adding an alternative compliance equation under the current standards, and technical and editorial changes. This action also finalizes a new EPA test method to measure isocyanate compounds in certain surface coatings. These amendments are being made under the authority of the Clean Air Act (CAA) and will improve the effectiveness of the rule. The amendments are environmentally neutral.

DATES: This final rule is effective on March 4, 2019. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of March 4, 2019.

ADDRESSES: The Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA–HQ–OAR–2016–0678. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *https://www.regulations.gov,* or in hard copy at the EPA Docket Center, EPA WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Mr. John Bradfield, Sector Policies and Programs Division (E143–03), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–3062; fax number: (919) 541–0516; and email address: *bradfield.john@epa.gov.* For specific information regarding the risk modeling methodology, contact Mr. James Hirtz, Health and Environmental Impacts Division (C539–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–0881; fax number: (919) 541–0840; and email address: *hirtz.james@epa.gov.* For information about the applicability of the NESHAP to a particular entity, contact Mr. John Cox, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, EPA WJC South Building, 1200 Pennsylvania Ave. NW, Mail Code 2221A, Washington, DC 20460; telephone number: (202) 564–1395; and email address: *cox.john@epa.gov.*

SUPPLEMENTARY INFORMATION: *Preamble acronyms and abbreviations.* We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

ANSI American National Standards Institute
ASTM American Society for Testing and Materials
ATSDR Agency for Toxic Substances and Disease Registry
CAA Clean Air Act
CDX Central Data Exchange
CEDRI Compliance and Emissions Data Reporting Interface
CFR Code of Federal Regulations
CORE Central Operations and Resources
CRA Congressional Review Act
EJ environmental justice
E.O. Executive Order
EPA Environmental Protection Agency
ERT Electronic Reporting Tool
EST Eastern Standard Time
FTIR Fourier Transform Infrared
HAP hazardous air pollutant(s)
HDI hexamethylene-1,6-diisocyanate
HI hazard index
HQ hazard quotient
IBR incorporation by reference
ICR information collection request
IRIS Integrated Risk Information System
km kilometers
MACT maximum achievable control technology
MDI methylene diphenyl diisocyanate
MI methyl isocyanate
MIR maximum individual risk
NAICS North American Industry Classification System
NCASI National Council for Air and Stream Improvement, Inc.
NEI National Emissions Inventory
NESHAP National Emission Standards for Hazardous Air Pollutants
No. number
NRDC Natural Resources Defense Council
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PDF portable document format
POM polycyclic organic matter
PRA Paperwork Reduction Act
QA quality assurance
QC quality control
REL reference exposure level
RFA Regulatory Flexibility Act
RIN Regulatory Information Number
RTR risk and technology review
SSM startup, shutdown, and malfunction
TDI 2,4-toluene diisocyanate
TOSHI target organ-specific hazard index
tpy tons per year
UMRA Unfunded Mandates Reform Act
U.S. United States
U.S.C. United States Code
UV ultraviolet
VCS voluntary consensus standards
WebFIRE Web Factor Information Retrieval System

Background information. On May 16, 2018, the EPA proposed revisions to the Surface Coating of Wood Building Products NESHAP based on our RTR. In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments are available in *Response to Public Comments on May 16, 2018 Proposal, December 2018,* Docket ID No. EPA–HQ–OAR–2016–0678. A ''track changes'' version of the regulatory language that incorporates the changes in this action is available in the docket.

Organization of this document. The information in this preamble is organized as follows:

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
C. Judicial Review and Administrative Reconsideration
II. Background
A. What is the statutory authority for this action?
B. What is the Surface Coating of Wood Building Products source category and how does the NESHAP regulate HAP emissions from the source category?
C. What changes did we propose for the Surface Coating of Wood Building Products source category in our May 16, 2018, proposal?
III. What is included in this final rule?
A. What are the final rule amendments based on the risk review for the Surface Coating of Wood Building Products source category?
B. What are the final rule amendments based on the technology review for the Surface Coating of Wood Building Products source category?
C. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?
D. What other changes have been made to the NESHAP?
E. What are the effective and compliance dates of the standards?
IV. What is the rationale for our final decisions and amendments for the Surface Coating of Wood Building Products source category?
A. Residual Risk Review for the Surface Coating of Wood Building Products Source Category
B. Technology Review for the Surface Coating of Wood Building Products Source Category
C. SSM
D. Alternative Compliance Equation
E. Emissions Testing
F. Electronic Reporting
G. EPA Test Method 326
H. IBR Under 1 CFR Part 51
I. Technical and Editorial Changes
V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted
A. What are the affected facilities?
B. What are the air quality impacts?
C. What are the cost impacts?
D. What are the economic impacts?
E. What are the benefits?
F. What analysis of environmental justice did we conduct?
G. What analysis of children's environmental health did we conduct?
VI. Statutory and Executive Order Reviews
A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs
C. Paperwork Reduction Act (PRA)
D. Regulatory Flexibility Act (RFA)
E. Unfunded Mandates Reform Act (UMRA)
F. Executive Order 13132: Federalism
G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51
K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
L. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Regulated entities. Categories and entities potentially regulated by this action are shown in Table 1 of this preamble.

TABLE 1—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

NESHAP and source category	NAICS [1] code
Surface Coating of Wood Building Products.	321211, 321212, 321218, 321219, 321911, 321999.

[1] North American Industry Classification System.

Table 1 of this preamble is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by the final action for the source category listed. To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this preamble.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: *https://www.epa.gov/stationary-sources-air-pollution/surface-coating-wood-building-products-national-emission-standard-1.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version and key technical documents at this same website.

Additional information is available on the RTR website at *https://www.epa.gov/ttn/atw/rrisk/rtrpg.html.* This information includes an overview of the RTR program, links to project websites for the RTR source categories, and detailed emissions and other data we used as inputs to the risk assessments.

C. Judicial Review and Administrative Reconsideration

Under CAA section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by May 3, 2019. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, EPA WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of hazardous air pollutants (HAP) from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. ''Major sources'' are those that emit, or have the potential to emit, any single HAP at a

rate of 10 tons per year (tpy) or more, or 25 tpy or more of any combination of HAP. For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including but not limited to those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less frequently than every 8 years, pursuant to CAA section 112(d)(6). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).[1] For more information on the statutory authority for this rule, see 83 FR 2274.

B. What is the Surface Coating of Wood Building Products source category and how does the NESHAP regulate HAP emissions from the source category?

The EPA promulgated the Surface Coating of Wood Building Products NESHAP on May 28, 2003 (See 68 FR 31746). The standards are codified at 40 CFR part 63, subpart QQQQ. The Wood Building Products Surface Coating industry consists of facilities that are engaged in the surface coating of wood building products, which means the application of coatings using, for example, roll coaters or curtain coaters in the finishing or laminating of any wood building product that contains more than 50 percent by weight wood or wood fiber, excluding the weight of any glass components, and is used in the construction, either interior or exterior, of a residential, commercial, or institutional building. Regulated operations include all processes and process units incorporating wood building products surface coating operations. The source category covered by this MACT standard currently includes 57 facilities.

C. What changes did we propose for the Surface Coating of Wood Building Products source category in our May 16, 2018, proposal?

On May 16, 2018, the EPA published a proposed rule in the **Federal Register** for the Surface Coating of Wood Building Products NESHAP, 40 CFR part 63, subpart QQQQ, that took into consideration the RTR analyses. In the proposed rule, we proposed revisions to the SSM provisions of the MACT rule in order to ensure that they are consistent with the Court decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), which vacated two provisions that exempted sources from the requirement to comply with otherwise applicable CAA section 112(d) emission standards during periods of SSM. We also proposed various other changes, including an alternative compliance calculation, electronic submittal of notifications, compliance reports, and performance test reports, a new EPA test method, IBR of several test methods, and various technical and editorial changes. Additionally, we requested comment on repeat emissions testing requirements for facilities that demonstrate compliance with the standards using add-on control devices and for any facilities using the alternative compliance equation under the emission rate without add-on controls option.

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Surface Coating of Wood Building Products source category. This action also finalizes other changes to the NESHAP, including an alternative compliance calculation equation that relies on periodic emissions testing; electronic submittal of notifications of compliance status, semiannual compliance reports, and performance test reports; a new EPA test method for isocyanates, EPA Method 326; IBR of several test methods (listed in section IV below); and various technical and editorial changes.

A. What are the final rule amendments based on the risk review for the Surface Coating of Wood Building Products source category?

The EPA proposed no changes to the 40 CFR part 63, subpart QQQQ NESHAP based on the risk review conducted pursuant to CAA section 112(f). We are finalizing our proposed determination that risks from the source category are acceptable, considering all of the health information and factors evaluated, and also considering risk estimation uncertainty. We are also finalizing our proposed determination that revisions to the current standards are not necessary to reduce risk to an acceptable level, to provide an ample margin of safety to protect public health, or to prevent an adverse environmental effect. The EPA received no new data or other information during the public comment period that affected our determinations. Therefore, we are not

[1] The Court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA,* 529 F.3d 1077, 1083 (D.C. Cir. 2008) (''If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.'').

requiring additional controls and, thus, are not making any revisions to the existing standards under CAA section 112(f).

B. What are the final rule amendments based on the technology review for the Surface Coating of Wood Building Products source category?

We determined that there are no developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. The EPA received no new data or other information during the public comment period that affected our determinations. Therefore, we are not finalizing revisions to the MACT standards under CAA section 112(d)(6).

C. What are the final rule amendments addressing emissions during periods of startup, shutdown, and malfunction?

In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the Court vacated portions of two provisions in the EPA's CAA section 112 ''General Provisions'' regulations governing the emissions of HAP during periods of SSM. Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously.

We have eliminated the SSM exemption in this rule. Consistent with *Sierra Club* v. *EPA,* the EPA has established standards in this rule that apply at all times. We have also revised Table 4 to Subpart QQQQ of Part 63 (the General Provisions applicability table) in several respects, as is explained in more detail below in section IV.C. For example, we have eliminated the incorporation of the General Provisions' requirement that the source develop an SSM plan. We have also eliminated and revised certain recordkeeping and reporting that is related to the SSM exemption as described in detail in the proposal and summarized below in section IV.C.

D. What other changes have been made to the NESHAP?

Other changes to the NESHAP that do not fall into the categories in the previous section include:

1. *Alternative compliance equation.* As proposed in response to a request for an alternative method of demonstrating compliance, we have amended the rule to add an alternative equation within the requirements for facilities meeting the ''emission rate without add-on controls'' compliance option under the current standards. The alternative is discussed further in section IV.D of this preamble.

2. *Emissions testing.* In response to comments and emissions tests discussed at proposal, we have amended the allowable compliance tests in the rule. Emissions testing is discussed further in section IV.E of this preamble.

3. *Electronic reporting.* As discussed at proposal, we are finalizing amendments to the reporting requirements in the rule to require electronic reporting for notifications of compliance status, compliance test reports, and semiannual reports. Electronic reporting is discussed further in section IV.F of this preamble.

4. *EPA Test Method 326.* As discussed at proposal, we are finalizing a new test method for isocyanate emissions. EPA Test Method 326 is discussed further in section IV.G and is included in appendix A to part 63 of this preamble.

5. *IBR under 1 CFR part 51.* We are incorporating several test methods by reference, as discussed further in section IV.H of this preamble.

6. *Technical and editorial changes.* We are finalizing technical and editorial changes, as discussed further in section IV.I of this preamble.

E. What are the effective and compliance dates of the standards?

The revisions to the MACT standards being promulgated in this action are effective on March 4, 2019. The compliance date for existing affected sources to comply with the revised requirements is no later than 180 days after March 4, 2019. Affected sources that commenced construction or reconstruction after May 16, 2018, are new sources. New sources must comply with the all of the standards immediately upon the effective date of the standard, March 4, 2019], or upon startup, whichever is later. In section IV.F of this preamble on Electronic Reporting, we discuss a semiannual reporting template that will become the required form for those reports 1 year after it is posted in the EPA's Compliance and Emissions Data Reporting Interface (CEDRI). The EPA expects to post the form on March 4, 2019. Consequently, 1 year or more after March 4, 2019, facilities subject to this standard will need to begin using this form for semiannual reports.

The EPA is finalizing that existing affected sources must comply with the amendments in this rulemaking no later than 180 days after March 4, 2019. The EPA is also finalizing that affected sources that commence construction or reconstruction after March 4, 2019 must comply with all requirements of the subpart, including the amendments being finalized, no later than March 4, 2019 or upon startup, whichever is later. All affected existing facilities would have to continue to meet the current requirements of 40 CFR part 63, subpart QQQQ, until the applicable compliance date of the amended rule. The final action is not a ''major rule'' as defined by 5 U.S.C. 804(2), so the effective date of the final rule is the promulgation date as specified in CAA sections 112(d)(10) and 112(f)(3). For existing sources, we are finalizing two changes that would impact ongoing compliance requirements for 40 CFR part 63, subpart QQQQ. As discussed elsewhere in this preamble, we are adding a requirement that the notification of compliance status, performance test results, and the semiannual reports using the new template be submitted electronically. We are also changing the requirements for SSM by removing the exemption from the requirements to meet the standard during SSM periods and by removing the requirement to develop and implement an SSM plan. Additionally, we are adding an optional new compliance demonstration equation that adds flexibility for meeting the standard, but this change does not affect ongoing compliance. Our experience with similar industries that are required to convert reporting mechanisms, install necessary hardware and software, become familiar with the process of submitting performance test results electronically through the EPA's CEDRI, test these new electronic submission capabilities, reliably employ electronic reporting, and convert logistics of reporting processes to different time-reporting parameters, shows that a time period of a minimum of 90 days, and more typically, 180 days, is generally necessary to successfully complete these changes. Our experience with similar industries further shows that this sort of regulated facility generally requires a time period of 180 days to read and understand the amended rule requirements; evaluate their operations to ensure that they can meet the standards during periods of startup and shutdown as defined in the rule and make any necessary adjustments; adjust parameter monitoring and recording systems to accommodate revisions; and update their operations to reflect the revised requirements. The EPA recognizes the confusion that multiple different compliance dates for individual requirements would create and the additional burden such an assortment of

dates would impose. From our assessment of the timeframe needed for compliance with the entirety of the revised requirements, the EPA considers a period of 180 days to be the most expeditious compliance period practicable, and, thus, is finalizing that existing affected sources be in compliance with all of this regulation's revised requirements within 180 days of the regulation's effective date.

IV. What is the rationale for our final decisions and amendments for the Surface Coating of Wood Building Products source category?

For each issue, this section provides a description of what we proposed and what we are finalizing for the issue, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. For all comments not discussed in this preamble, comment summaries and the EPA's responses can be found in the comment summary and response document available in the docket, Docket ID No. EPA–HQ–OAR–2016–0678.

A. Residual Risk Review for the Surface Coating of Wood Building Products Source Category

1. What did we propose pursuant to CAA section 112(f) for the Surface Coating of Wood Building Products source category?

For the 40 CFR part 63, subpart QQQQ category risk assessment conducted at proposal, the EPA estimated risks based on actual and allowable emissions from wood building products surface coating sources. Allowable emissions at proposal were estimated to be equal to actual emissions. The estimated inhalation cancer risk to the individual most exposed to emissions from the source category was 6-in-1 million at proposal, at one facility. The assessment showed that approximately 800 people faced an increased cancer risk greater than 1-in-1 million due to inhalation exposure to HAP emissions from this source category. The risk analysis at proposal indicated very low cancer incidence (0.0006 excess cancer cases per year, or one excess case every 1,667 years), as well as low potential for adverse chronic noncancer health effects with a hazard index (HI) of 0.05 for both actual and allowable emissions. The acute screening assessment indicated two facilities with a maximum hazard quotient (HQ) equal to 1 based upon a reference exposure level (REL) for formaldehyde. Therefore, we found there was little potential concern for chronic or acute noncancer health impacts. The multipathway risk assessment indicated no significant potential for exposure from persistent bio-accumulative HAP (PB–HAP) emissions from the source category.

Considering all of the health risk information, the EPA proposed that the risks from the Surface Coating of Wood Building Products source category were acceptable. Although we proposed acceptable risk, risk estimates for approximately 800 people in the exposed population were above 1-in-1 million, caused by formaldehyde emissions from one facility. The maximum acute risk at proposal was an HQ of 1, also associated with formaldehyde from the same facility with the highest chronic risk. As a result, we further considered whether the MACT standards for this source category provide an ample margin of safety to protect public health. Our technology review did not identify any new practices, controls, or process options that were being used in this industry, or in other industries, that would be cost effective and result in further reduction of formaldehyde emissions. Because no new controls, technologies, processes, or work practices were identified to reduce formaldehyde emissions and the risk assessment determined that the health risks associated with HAP emissions remaining after implementation of the Surface Coating of Wood Building Products MACT were acceptable, we proposed that the current standards protect public health with an ample margin of safety.

2. How did the risk review change for the Surface Coating of Wood Building Products source category?

In response to comments on the proposed 40 CFR part 63, subpart QQQQ, RTR, we reviewed our facility list and made adjustments, adding five facilities and removing four facilities. The five facilities added had responded to a separate EPA survey, indicating that 40 CFR part 63, subpart QQQQ applied to their facilities. The HAP emissions inventory for the source category was revised to reflect these changes to the facility list. Further, we found that 40 CFR part 63, subpart QQQQ did not apply to four facilities. As such, we removed these four facilities from the facility list. In response to comments received, we also reviewed our HAP data and added polycyclic organic matter (POM) to the HAP emission inventory for the source category. At proposal, we set allowable HAP emissions as being equal to actual HAP emissions due to the nature of compliance choices made by facilities in the category. In response to comments, we reviewed this approach and decided to estimate allowable emissions using a 1.6 multiple of actual emissions. The multiplier was derived from source category capacity usage information in the U.S. Census of Manufacturers. In response to comments, we also decided to use the more conservative multiplier of 10 times actual emissions to model acute health impacts. See the *Addendum to Preparation of the Residual Risk Modeling Input File for Subpart QQQQ,* in the docket for this rule, EPA–HQ–OAR–2016–0678, for more details regarding these changes. In response to comments received, we also considered whether a refined risk modeling analysis would better inform the EPA about the impact on disadvantaged communities from HAP emissions from the source category. The changes in the facility list, HAP inventory, allowable and acute emission estimates, and environmental justice (EJ) concerns led the EPA to prepare and run a new modeling file and prepare a revised risk assessment, *Residual Risk Assessment for the Surface Coating of Wood Building Products Source Category in Support of the 2018 Risk and Technology Review Final Rule,* which is available in the docket for the rule.

The revised risk assessment for the source category indicated that human health impacts for both chronic and acute risks were lower than stated at proposal. The results of the risk assessment showed that risks based on actual emissions did not exceed a maximum individual risk (MIR) of 1-in-1 million for cancer and resulted in an HI of 0.02 for noncancer. The results of the final risk assessment also showed lower risks based upon allowable emissions with a cancer MIR of 1-in-1 million and a noncancer HI of 0.03. The revised risk assessment also showed lower acute risks than stated at proposal with a maximum acute noncancer HQ of 0.6.

Table 2 of this preamble provides an overall summary of the results of the inhalation risk assessment, as discussed in this section of this preamble. See the *Addendum to Preparation of the Residual Risk Modeling Input File for Subpart QQQQ,* in the docket for this rule, Docket ID No. EPA–HQ–OAR–2016–0678, for more details regarding preparation of the modeling file.

TABLE 2—SURFACE COATING OF WOOD BUILDING PRODUCTS INHALATION RISK ASSESSMENT RESULTS [1]

Risk assessment	Number of facilities [2]	Maximum individual cancer risk (in 1 million) [3]	Estimated population at increased risk of cancer ≥1-in-1 million	Estimated annual cancer incidence (cases per year)	Maximum chronic noncancer TOSHI [4]	Maximum screening acute noncancer HQ [5]
Baseline Actual Emissions:						
Source Category	50	<1	0	0.0004	0.02	0.6
Baseline Allowable Emissions:						
Source Category	50	1	700	0.0007	0.03	.....

[1] Based on actual and allowable emissions for facilities subject to 40 CFR part 63, subpart QQQQ. See *Residual Risk Assessment for the Surface Coating of Wood Building Products Source Category in Support of the 2018 Risk and Technology Review Final Rule,* in the docket for this rule, EPA–HQ–OAR–2016–0678, for more details.

[2] Number of facilities evaluated in the risk assessment. Seven facilities in the category reported no HAP emissions from coatings subject to 40 CFR part 63, subpart QQQQ. Facilities that did not emit any HAP subject to 40 CFR part 63, subpart QQQQ were only modeled for whole-facility HAP emissions. Two facilities in the source category reported zero HAP emissions facility-wide and were not modeled.

[3] Maximum individual excess lifetime cancer risk due to HAP emissions from the source category facilities. The risk driver for the source category is naphthalene.

[4] Maximum target organ-specific hazard index (TOSHI). The target organ with the highest TOSHI for the source category is the respiratory system. The risk drivers for the source category are triethylamine and naphthalene.

[5] The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of HQ values. HQ values shown use the lowest available acute threshold value, which, in most cases, is the REL. When an HQ exceeds 1 in the acute risk screening assessment, we conduct further analysis to determine the highest off-site impact. The maximum acute noncancer risk driver is formaldehyde.

The inhalation risk modeling performed to estimate risks based on actual and allowable emissions relied primarily on emissions data from the National Emissions Inventory (NEI). The results of the inhalation cancer risk assessment, as shown in Table 2 of this preamble, indicate that the MIR could be up to 1-in-1 million for allowable emissions under the current standard, with naphthalene emissions from solvent evaporation associated with spray paint operations as the major contributor to the MIR. The total estimated cancer incidence from wood building product coating sources based on actual emission levels is 0.0004 excess cancer cases per year or one case every 2,500 years, with emissions of naphthalene and ethylbenzene contributing to the cancer incidence. In addition, we estimate that approximately 700 people have cancer risks at 1-in-1 million based on allowable emissions.

The maximum modeled chronic noncancer HI (TOSHI) value for the source category based on actual emissions is estimated to be 0.02, with emissions of triethylamine and naphthalene contributing to the TOSHI. The target organ affected is the respiratory system. No people are estimated to have a noncancer HI above 1 as a result of emissions from this source category.

3. What key comments did we receive on the risk review, and what are our responses?

We received two comments on our proposed risk assessment. One stakeholder supported our risk assessment proposal and further suggested that the Integrated Risk Information System (IRIS) dose response factors for formaldehyde, the principle risk driver in the category, were overly conservative and should be re-evaluated. Another stakeholder disagreed with our assessment, characterizing it as arbitrary because (1) it exceeded the 1-in-1 million CAA presumption of acceptability from CAA section 112(f)(2), and (2) the health impacts of the risk above 1-in-1 million were concentrated in minority and lower income neighborhoods, and, thus, creating what the commenter considered an environmental justice issue.

As stated in our response to comments,[2] we found the risk from HAP exposure from emission sources in this category to be acceptable. The cancer dose-response value used in the risk assessment for formaldehyde is the current peer reviewed IRIS value. The chronic noncancer dose-response value used for formaldehyde is from the Agency for Toxic Substances and Disease Registry (ATSDR). At the time this analysis was performed, these values were deemed to represent the best science.

Regarding the comments to risk on disadvantaged communities, under Executive Order 12898, the EPA is directed to the greatest extent practicable and permitted by law, to make EJ part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low income populations in the U.S. Consistent with Executive Order 12898 and the Presidential Memorandum [3] that accompanies it, the EPA's EJ policies promote justice by focusing attention and EPA efforts on addressing the types of EJ harms and risks that are prevalent among minority, low-income, and indigenous populations. Executive Order 12898 and the EPA's EJ policies do not mandate particular outcomes from an action, but they require that decisions involving the action be informed by a consideration of EJ issues. With respect to this rule, the EPA found that the original NESHAP meets the CAA section 112(f)(2) standard for providing an ample margin of safety for all populations in close proximity to these sources, including minority and low-income populations.

4. What is the rationale for our final approach and final decisions for the risk review?

As noted in our proposal, the EPA sets standards under CAA section 112(f)(2) using ''a two-step standard-setting approach, with an analytical first step to determine an 'acceptable risk' that considers all health information, including risk estimation uncertainty, and includes a presumptive limit on MIR of ''approximately 1-in-10 thousand'' (see 54 FR 38045, September 14, 1989). We weigh all health risk factors in our risk acceptability

[2] See *Response to Public Comments on May 16, 2018 Proposal, December 2018,* Docket ID No. EPA–HQ–OAR–2016–0678.

[3] Memorandum for the Heads of All Departments and Agencies from William Clinton, February 11, 1994. *Executive Order on Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.*

determination, including the cancer MIR, cancer incidence, the maximum cancer TOSHI, the maximum acute noncancer HQ, the extent of noncancer risks, the distribution of cancer and noncancer risks in the exposed population, and the risk estimation uncertainties.

Our final risk assessment was revised based on comments we received at proposal. It included updated facility information, HAP emissions, and production information (see section IV.A.2 of this preamble). The total emissions of HAP for the source category are approximately 270 tpy. The results of the chronic inhalation cancer risk assessment based on actual emissions, the total estimated cancer incidence from allowable emissions in this source category, and the acute HQ are discussed in section IV.A.2 and in Table 2 of this preamble. In evaluating the potential for multipathway effects from PB–HAP, including carcinogenic emissions of arsenic and POM and non-carcinogenic emissions of cadmium, lead, and mercury from the source category, the risk assessment indicates no significant potential for multipathway effects.

We concluded, based on all the health risk information and factors discussed at proposal, that the risks from the Surface Coating of Wood Building Products source category were acceptable. As noted above, the information in the final risk assessment shows lower risk indicators than indicated at proposal. Consequently, the EPA is finalizing an acceptable risk determination for the category. We conducted an analysis to determine if the current emissions standards provide an ample margin of safety to protect public health. Under the ample margin of safety analysis,[4] the EPA considers all health factors evaluated in the risk assessment and evaluates the cost and feasibility of available control technologies and other measures (including the controls, measures, and costs reviewed under the technology review) that could be applied to this source category to further reduce the risks (or potential risks) due to emissions of HAP identified in our risk assessment. In this analysis, we considered the results of the technology review, risk assessment, and other aspects of our MACT rule review to determine whether there are any cost-effective controls or other measures that would reduce emissions further to provide an ample margin of safety with respect to the risks associated with these emissions.

[4] See CAA section 112(f)(2).

As noted, we consider the risks from this source category to be acceptable. However, risk estimates for approximately 700 people in the exposed population are at 1-in-1 million, based on allowable naphthalene emissions from one facility. As a result, we further considered whether the MACT standards for this source category provide an ample margin of safety to protect public health.

At proposal, our ample margin of safety review was informed by the results of our technology review which did not identify any developments in practices, controls, or process options that are being used in this industry, or in other industries, that would be cost effective and result in further emissions reductions. Similarly, our review of the operating permits for major sources subject to the Surface Coating of Wood Building Products MACT did not reveal any facilities with limits set below the current new or existing source limits (Tables 1 and 2 to Subpart QQQQ of Part 63). Limits set below the current standards would have been an indication that improved controls or lower emission-compliant coatings were available. Additionally, our review of the Reasonably Available Control Technology/Best Available Control Technology/Lowest Achievable Emission Rate Clearinghouse identified three sources that are potentially covered under 40 CFR part 63, subpart QQQQ, but none contained new control methods. Because no developments in controls, technologies, processes, or work practices were identified to reduce naphthalene emissions and the risk assessment determined that the health risks associated with HAP emissions remaining after implementation of the Surface Coating of Wood Building Products MACT were acceptable, we are finalizing our risk review determination that the current standards protect public health with an ample margin of safety.

B. Technology Review for the Surface Coating of Wood Building Products Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Surface Coating of Wood Building Products source category?

Our review of the developments in technology for the Surface Coating of Wood Building Products source category did not reveal any changes in practices, processes, and controls. In the original NESHAP, we noted that the most prevalent form of emission control for surface coating of wood building products is the use of low-volatile organic compounds and low-HAP coatings, such as waterborne or ultraviolet (UV)-cured coatings. That continues to be the prevalent compliance approach, with less than 10 percent of source category facilities using add-on control to reduce HAP emissions. Because our review did not identify any developments in practices, processes, or controls to further reduce emissions in the category beyond the level required by the current NESHAP, we proposed that no revisions to the NESHAP are necessary pursuant to CAA section 112(d)(6).

2. How did the technology review change for the Surface Coating of Wood Building Products source category?

The technology review did not change from proposal. Therefore, we are finalizing our proposed determination that no revisions to the NESHAP are necessary pursuant to CAA section 112(d)(6).

3. What key comments did we receive on the technology review, and what are our responses?

We received no comments that identified improved control technology, work practices, operational procedures, process changes, or pollution prevention approaches to reduce emissions in the category since promulgation of the current NESHAP. We received two comments on our proposed technology review. One stakeholder supported our review, while another stakeholder disagreed with our assessment, holding that the new coating application which led to the proposal of an alternative compliance equation constituted a change that should have been adopted across the category (see Docket ID No. EPA–HQ–OAR–2016–0678).

As stated in our comment response (see Docket ID No. EPA–HQ–OAR–2016–0678), we are finalizing the conclusion that there have been no advances in practices, processes, or controls since promulgation in 2003 that justify changes to the stringency of the standards for 40 CFR part 63, subpart QQQQ sources.

At proposal, we explained how the coating planned for use by the facility submitting the alternative monitoring request is similar to other low-HAP coatings in that it uses a liquid catalyst to affect the same type of chemical and physical changes as UV light in the UV-curable coatings, which are low-HAP coatings that predate and were considered during development of the original 40 CFR part 63, subpart QQQQ NESHAP. Regardless of this explanation, we see how the commenter

may have misconstrued some of the discussion in the proposal's supporting memorandum regarding the coating technology and the new compliance equation. The updated memorandum, *Technology Review for the Surface Coating of Wood Building Products Source Category—Final Rule,* available in the docket for this rule, EPA–HQ–OAR–2016–0678, clarifies the information used for the technology review. The technology basis of the coating technology for which the new compliance equation we finalize here is not broadly applicable. It is simply one of many technology approaches that can be used to meet the standard. Consequently, we did not propose the alternate compliance equation as a ''development'' under CAA section 112(d)(6), nor are we finalizing it as such. Even if the EPA were to consider the new coating to be a development within the meaning of CAA section 112(d)(6), the EPA has discretion to determine when it is ''necessary'' to revise emission standards under the statute. In this case, it would not be necessary to revise the numeric emission standards in Tables 1 or 2 to Subpart QQQQ of Part 63, in order to accommodate the alternative monitoring request from one facility that fits within the overarching compliance options included in the rule (*i.e.,* the ''emission rate without add-on controls'' option).

4. What is the rationale for our final approach for the technology review?

Our technology review did not identify any changes in practices, processes, or control technologies that would reduce emissions in this category. We did not identify any control equipment not previously identified; improvements to existing controls; work practices, process changes, or operational procedures not previously considered; or any new pollution prevention alternatives for this same category. We also did not find any changes in the cost of applying controls previously considered in this same category. Consequently, we have determined that no revisions to the NESHAP are necessary pursuant to CAA section 112(d)(6).

C. SSM

In its 2008 decision in *Sierra Club* v. *EPA,* 551 F.3d 1019 (D.C. Cir. 2008), the Court vacated portions of two provisions in the EPA's CAA section 112 General Provisions regulations governing the emissions of HAP during periods of SSM. Specifically, the Court vacated the SSM exemption contained in 40 CFR 63.6(f)(1) and 40 CFR 63.6(h)(1), holding that under section 302(k) of the CAA, emissions standards or limitations must be continuous in nature and that the SSM exemption violates the CAA's requirement that some CAA section 112 standards apply continuously.

We are finalizing the elimination of the SSM exemption in this rule. The SSM provisions appear at 40 CFR 63.4700, 40 CFR 63.4720, and in Table 4 to Subpart QQQQ of Part 63. Consistent with *Sierra Club* v. *EPA,* we are finalizing that the standards in this rule apply at all times. We are also finalizing several revisions to Table 4 (the General Provisions Applicability Table), as explained in more detail below. For example, we are eliminating incorporation of the General Provisions' requirement that the source develop an SSM plan. We also are eliminating and revising certain recordkeeping and reporting requirements related to the SSM exemption, as further described below.

The EPA has attempted to ensure that the provisions we are eliminating are inappropriate, unnecessary, or redundant in the absence of the SSM exemption. The EPA believes the removal of the SSM exemption creates no additional burden to facilities regulated under the Surface Coating of Wood Building Products NESHAP. Deviations addressed in current SSM plans are now required to be reported in the semiannual compliance report (40 CFR 63.4720). Facilities no longer need to develop an SSM plan or keep it current (Table 4 to Subpart QQQQ of Part 63). Facilities also no longer have to file SSM reports for deviations not described in the their SSM plan (40 CFR 63.4720(c)(2)).

Periods of startup and shutdown. In finalizing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, is not finalizing alternate standards for those periods.

For add-on control systems, the Surface Coating of Wood Building Products NESHAP requires the measurement of thermal oxidizer operating temperature or catalytic oxidizer average temperature across the catalyst bed as well as other types of parameter monitoring. Parameter limits now apply at all times, including during periods of startup and shutdown. The Surface Coating of Wood Building Products NESHAP requires thermal oxidizer or catalytic oxidizer operating temperature and operating parameters for other add-on control devices to be recorded at least once every 15 minutes. The Surface Coating of Wood Building Products NESHAP specifies in 40 CFR 63.4763(c) that if an operating parameter is out of the allowed range, this is a deviation from the operating limit and must be reported as specified in 40 CFR 63.4710(c)(6) and 63.4720(a)(7).

Our permit review of the facilities using add-on control as a compliance approach indicated that all were required, by permit, to have their control system in operation during all time periods when coating processes were operational. The 2003 rule requires compliance based on a 12-month rolling average emissions calculation. Periods of startup and shutdown were included, but, because of operational requirements in the category, are a very small component of the emissions calculation and have little, if any, impact on the 12-month rolling average. Therefore, we are not finalizing separate standards for startup and/or shutdown periods.

Periods of malfunction. Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. Malfunctions, in contrast, are neither predictable nor routine. Instead, they are, by definition, sudden, infrequent, and not reasonably preventable failures of emissions control, process, or monitoring equipment. (40 CFR 63.2, definition of malfunction). The EPA interprets CAA section 112 as not requiring emissions that occur during periods of malfunction to be factored into development of CAA section 112 standards and this reading has been upheld as reasonable by the Court in *U.S. Sugar Corp.* v. *EPA,* 830 F.3d 579, 606–610 (2016). Under CAA section 112, emissions standards for new sources must be no less stringent than the level ''achieved'' by the best controlled similar source and for existing sources generally must be no less stringent than the average emission limitation ''achieved'' by the best performing 12 percent of sources in the category. There is nothing in CAA section 112 that directs the Agency to consider malfunctions in determining the level ''achieved'' by the best performing sources when setting emission standards. As the Court has recognized, the phrase ''average emissions limitation achieved by the best performing 12 percent of'' sources ''says nothing about how the performance of the best units is to be calculated.'' *National Association of Clean Water Agencies* v. *EPA,* 734 F.3d 1115, 1141 (D.C. Cir. 2013). While the EPA accounts for variability in setting emissions standards, nothing in CAA section 112 requires the Agency to consider malfunctions as part of that analysis. The EPA is not required to treat a malfunction in the same manner as the type of variation in performance

that occurs during routine operations of a source. A malfunction is a failure of the source to perform in ''normal or usual manner,'' and no statutory language compels the EPA to consider such events in setting CAA section 112 standards.

As the Court recognized in *U.S. Sugar Corporation,* accounting for malfunctions in setting standards would be difficult, if not impossible, given the myriad different types of malfunctions that can occur across all sources in the category and given the difficulties associated with predicting or accounting for the frequency, degree, and duration of various malfunctions that might occur. *Id.* at 608 (''the EPA would have to conceive of a standard that could apply equally to the wide range of possible boiler malfunctions, ranging from an explosion to minor mechanical defects. Any possible standard is likely to be hopelessly generic to govern such a wide array of circumstances.''). As such, the performance of units that are malfunctioning is not ''reasonably'' foreseeable. See, *e.g., Sierra Club* v. *EPA,* 167 F.3d 658, 662 (D.C. Cir. 1999) (''The EPA typically has wide latitude in determining the extent of data-gathering necessary to solve a problem. We generally defer to an agency's decision to proceed on the basis of imperfect scientific information, rather than to 'invest the resources to conduct the perfect study.' ''). See also, *Weyerhaeuser* v. *Costle,* 590 F.2d 1011, 1058 (D.C. Cir. 1978) (''In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.''). In addition, emissions during a malfunction event can be significantly higher than emissions at any other time of source operation. For example, if an air pollution control device with 99-percent removal goes off-line as a result of a malfunction (as might happen if, for example, the bags in a baghouse catch fire) and the emission unit is a steady state type unit that would take days to shut down, the source would go from 99-percent control to zero control until the control device was repaired. The source's emissions during the malfunction would be 100 times higher than during normal operations. As such, the emissions over a 4-day malfunction period would exceed the annual emissions of the source during normal operations. As this example illustrates, accounting for malfunctions could lead to standards that are not reflective of (and significantly less stringent than) levels that are achieved by a well-performing non-malfunctioning source. It is reasonable to interpret CAA section 112 to avoid such a result. The EPA's approach to malfunctions is consistent with CAA section 112 and is a reasonable interpretation of the statute.

Although no statutory language compels the EPA to set standards for malfunctions, the EPA has the discretion to do so where feasible. For example, in the Petroleum Refinery Sector RTR, the EPA established a work practice standard for unique types of malfunction that result in releases from pressure relief devices or emergency flaring events because information regarding petroleum refinery sources was available to determine that such work practices reflected the level of control that applies to the best performing sources in that source category. See 80 FR 75178, 75211–75214 (December 1, 2015). The EPA considered whether circumstances warrant setting work practice standards for a particular type of malfunction and, if so, whether the EPA has sufficient information to identify the relevant best performing sources and establish a standard for such malfunctions.

In the event that a source fails to comply with the applicable CAA section 112 standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 112 standard was, in fact, sudden, infrequent, not reasonably preventable, and was not instead caused, in part, by poor maintenance or careless operation. 40 CFR 63.2 (definition of malfunction).

If the EPA determines in a particular case that an enforcement action against a source for violation of an emission standard is warranted, the source can raise any and all defenses in that enforcement action and the federal district court will determine what, if any, relief is appropriate. The same is true for citizen enforcement actions. Similarly, the presiding officer in an administrative proceeding can consider any defense raised and determine whether administrative penalties are appropriate.

In summary, the EPA's interpretation of the CAA and, in particular, CAA section 112 is reasonable and encourages practices that will avoid malfunctions. Administrative and judicial procedures for addressing exceedances of the standards fully recognize that violations may occur despite good faith efforts to comply and can accommodate those situations. *U.S. Sugar Corporation* v. *EPA,* 830 F.3d 579, 606–610 (2016).

1. General Duty

We are finalizing revisions to the General Provisions table (Table 4) entry for 40 CFR 63.6(e)(1) and (2) by redesignating it as 40 CFR 63.6(e)(1)(i) and changing the ''yes'' in column 3 to a ''no.'' Section 63.6(e)(1)(i) describes the general duty to minimize emissions. Some of the language in that section is no longer necessary or appropriate considering the elimination of the SSM exemption. We are instead adding general duty regulatory text at 40 CFR 63.4700(b) that reflects the general duty to minimize emissions while eliminating the reference to periods covered by an SSM exemption. The previous language in 40 CFR 63.6(e)(1)(i) characterized what the general duty entails during periods of SSM. With the elimination of the SSM exemption, there is no need to differentiate between normal operations and SSM events in describing the general duty. Therefore, the language the EPA is finalizing for 40 CFR 63.4700(b) does not include that language from 40 CFR 63.6(e)(1).

We are also revising the General Provisions table (Table 4) to add an entry for 40 CFR 63.6(e)(1)(ii) and include a ''no'' in column 3. Section 63.6(e)(1)(ii) imposes requirements that are not necessary with the elimination of the SSM exemption or are redundant with the general duty requirement being added at 40 CFR 63.4700(b). We are also finalizing revisions to the General Provisions table (Table 4) to add an entry for 40 CFR 63.6(e)(1)(iii) and include a ''yes'' in column 3, which became necessary with the elimination of the SSM. Finally, we are finalizing revisions to the General Provisions table (Table 4) to add an entry for 40 CFR 63.6(e)(2) and include a ''no'' in column 3. This paragraph is reserved and is not applicable to 40 CFR part 63, subpart QQQQ.

2. SSM Plan

We are finalizing revisions to the General Provisions table (Table 4) to add an entry for 40 CFR 63.6(e)(3) and

include a ''no'' in column 3. Generally, these paragraphs require development of an SSM plan and specify SSM recordkeeping and reporting requirements related to the SSM plan. As noted, the EPA is finalizing removal of the SSM exemptions. Therefore, affected units will be subject to an emission standard during such events. The applicability of a standard during such events will ensure that sources have ample incentive to plan for and achieve compliance, and, thus, the SSM plan requirements are no longer necessary.

3. Compliance With Standards

We are finalizing revisions to the General Provisions table (Table 4) entries for 40 CFR 63.6(f) by redesignating this section as 40 CFR 63.6(f)(1) and including a ''no'' in column 3. The previous language in 40 CFR 63.6(f)(1) excluded sources from non-opacity standards during periods of SSM, while the previous language in 40 CFR 63.6(h)(1) excluded sources from opacity standards during periods of SSM. As discussed above, the Court in *Sierra Club* vacated the exemptions contained in this provision and held that the CAA requires that some CAA section 112 standards apply continuously. Consistent with *Sierra Club,* the EPA is finalizing the revised standards in this rule to apply at all times.

4. Performance Testing

We are finalizing revisions to the General Provisions table (Table 4) entry for 40 CFR 63.7(e) by redesignating it as 40 CFR 63.7(e)(1) and including a ''yes'' in column 3. Section 63.7(e)(1) describes performance testing requirements. Section 63.4764(a) of the rule specifies that performance testing must be conducted when the coating operation, emission capture system, and add-on control device are operating at representative conditions. You must document why the conditions represent normal operation. As in 40 CFR 63.7(e)(1), performance tests conducted under this subpart should not be conducted during periods of startup, shutdown, or malfunction because conditions during malfunctions are often not representative of normal operating conditions. The EPA is finalizing added language that requires the owner or operator to record the process information that is necessary to document operating conditions during the test and include in such record an explanation to support that such conditions represent normal operations. Section 63.7(e) requires that the owner or operator make available to the Administrator such records ''as may be necessary to determine the condition of the performance test'' available to the Administrator upon request, but does not specifically require the information to be recorded. The added regulatory text to this provision that the EPA is finalizing builds on that requirement and makes explicit the requirement to record the information.

5. Monitoring

We are finalizing revisions to the General Provisions table (Table 4) by redesignating 40 CFR 63.8(c) as 40 CFR 63.8(c)(1), adding entries for 40 CFR 63.8(c)(1)(i) through (iii), and including ''no'' in column 3 for paragraphs (i) and (iii). The cross-references to the general duty and SSM plan requirements in those subparagraphs are not necessary considering other requirements of 40 CFR 63.8 that require good air pollution control practices (40 CFR 63.8(c)(1)) and that set out the requirements of a quality control (QC) program for monitoring equipment (40 CFR 63.8(d)).

6. Recordkeeping

We are finalizing revisions to the General Provisions table (Table 4) by adding an entry for 40 CFR 63.10(b)(2)(i) and including a ''no'' in column 3. Section 63.10(b)(2)(i) describes the recordkeeping requirements during startup and shutdown. These recording provisions are no longer necessary because the EPA is finalizing that recordkeeping and reporting applicable to normal operations will apply to startup and shutdown. Special provisions applicable to startup and shutdown, such as a startup and shutdown plan, have been removed from the rule (with exceptions discussed below), thereby reducing the need for additional recordkeeping for startup and shutdown periods.

We are finalizing revisions to the General Provisions table (Table 4) by adding an entry for 40 CFR 63.10(b)(2)(iv) and (v) and including a ''no'' in column 3. When applicable, the provision requires sources to record actions taken during SSM events when actions were inconsistent with their SSM plan. The requirement is no longer appropriate because SSM plans will no longer be required.

We are also finalizing revisions to the General Provisions table (Table 4) by adding an entry for 40 CFR 63.10(c)(15) and including a ''no'' in column 3. The EPA is finalizing that 40 CFR 63.10(c)(15) no longer applies. When applicable, the provision allows an owner or operator to use the affected source's SSM plan or records kept to satisfy the recordkeeping requirements of the SSM plan, specified in 40 CFR 63.6(e), to also satisfy the requirements of 40 CFR 63.10(c)(10) through (12). The EPA is finalizing elimination of this requirement because SSM plans would no longer be required, and, therefore, 40 CFR 63.10(c)(15) no longer serves any useful purpose for affected units.

7. Reporting

We are finalizing revisions to the General Provisions table (Table 4) entry for 40 CFR 63.10(d)(5) by changing the ''yes'' in column 3 to a ''no.'' Section 63.10(d)(5) describes the reporting requirements for startups, shutdowns, and malfunctions. To replace the General Provisions reporting requirement for malfunctions, the EPA is finalizing replacing the SSM report under 40 CFR 63.10(d)(5) with the existing reporting requirements under 40 CFR 63.4720(a). The replacement language differs from the General Provisions requirement in that it eliminates periodic SSM reports as a stand-alone report. We are finalizing language that requires sources that fail to meet an applicable standard at any time to report the information concerning such events in the semiannual report to be required under the final rule. We are finalizing that the report must contain the number, date, time, duration, and the cause of such events (including unknown cause, if applicable), a list of the affected source or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions. Examples of such methods would include mass balance calculations, measurements when available, or engineering judgment based on known process parameters. The EPA is finalizing this requirement to ensure that there is adequate information to determine compliance, to allow the EPA to determine the severity of the failure to meet an applicable standard, and to provide data that may document how the source met the general duty to minimize emissions during a failure to meet an applicable standard.

We will no longer require owners or operators to determine whether actions taken to correct a malfunction are consistent with an SSM plan, because plans would no longer be required. The final amendments, therefore, eliminate the cross-reference to 40 CFR 63.10(d)(5)(i) that contains the description of the previously required SSM report format and submittal schedule from this section. These specifications are no longer necessary because the events will be reported in

otherwise required reports with similar format and submittal requirements.

The final amendments also eliminate the cross-reference to 40 CFR 63.10(d)(5)(ii). Section 63.10(d)(5)(ii) describes an immediate report for startups, shutdowns, and malfunctions when a source failed to meet an applicable standard, but did not follow the SSM plan. We no longer require owners and operators to report when actions taken during a startup, shutdown, or malfunction were not consistent with an SSM plan because plans would no longer be required.

D. Alternative Compliance Equation

The EPA proposed the option of using a HAP emission factor based on site-specific measurement of HAP emissions to demonstrate compliance with the emission rate without add-on controls compliance option, instead of assuming that all HAP in the coating is emitted to the atmosphere. As discussed below, we are finalizing a new compliance calculation approach in this rulemaking to allow any facility using a similar process to use the approach without requiring the submittal of an alternative monitoring request to the EPA under the provisions of 40 CFR 63.8(f). The final amendment adds compliance flexibility, but does not alter the originally promulgated emission standards in Tables 1 and 2 to Subpart QQQQ of Part 63.

We are finalizing a new equation within the existing compliance demonstration calculations to more adequately represent the HAP amounts emitted by this type of surface coating or any similar coating.

E. Emissions Testing

The EPA is finalizing amendments to the Surface Coating of Wood Building Products NESHAP that provide an additional compliance demonstration equation. Facilities using the alternative compliance demonstration equation (40 CFR 63.4751(i)) of the emission rate without add-on controls option are required to conduct an initial performance test to demonstrate compliance. Those same facilities are also required to conduct repeat performance testing every 5 years to update/verify the process-specific emission factor used to demonstrate continuing compliance for the new alternative equation (see 40 CFR 63.4752(e)).

F. Electronic Reporting

The EPA is requiring owners and operators of wood building product surface coating facilities to submit electronic copies of the required notification of compliance status, performance test results, and semiannual compliance status reports through the EPA's Central Data Exchange (CDX) using CEDRI. The final rule requires that performance test reports be submitted to CEDRI using the Electronic Reporting Tool (ERT). The final rule requires owners and operators to submit any future notification of compliance status (*e.g.,* for a new coating process) in portable document format (PDF) to CEDRI. For semiannual compliance status reports, in conjunction with the final rule, owners and operators are provided a spreadsheet template to submit information to CEDRI. The template is expected to facilitate reporting and improve reporting consistency. Facilities will be required to use the template to file their semiannual reports 1 year after the reporting template becomes available in CEDRI. The EPA expects to post the reporting template in conjunction with the final rule, so facilities can expect the requirement to begin for the semiannual reporting using the template by March 4, 2020.

The electronic submittal of the reports addressed in this rulemaking will increase the usefulness of the data contained in these reports; is in keeping with current trends in data availability, accountability, and transparency; will further assist in the protection of public health and the environment; will improve compliance by facilitating the ability of regulated facilities to demonstrate compliance with the requirements and by facilitating the ability of delegated state, local, tribal, and territorial air agencies and the EPA to assess and determine compliance; and will ultimately reduce burden on regulated facilities, delegated air agencies, and the EPA. Electronic reporting eliminates paper-based, manual processes, thereby saving time and resources; simplifying data entry; eliminating redundancies; minimizing data reporting errors; and providing data quickly and accurately to the affected facilities, air agencies, the EPA, and the public. A more streamlined and accurate review of performance test data will become available to the public through the EPA's Web Factor Information Retrieval System (WebFIRE).

In summary, in addition to supporting regulation development, control strategy development, and other air pollution control activities, having an electronic database populated with performance test data will save industry, state, local, tribal agencies, and the EPA significant time, money, and effort while improving the quality of emission inventories and air quality regulations.

For a more thorough discussion of electronic reporting, see the discussion in the preamble of the proposal, at 83 FR 22754, and the memorandum titled *Electronic Reporting Requirements for New Source Performance Standards (NSPS) and National Emission Standards for Hazardous Air Pollutants (NESHAP) Rules,* available in Docket ID No. EPA–HQ–OAR–2016–0678.

G. EPA Test Method 326

We are finalizing EPA Method 326 to improve test methodology related to volatile organic HAP content measured in certain surface coatings containing isocyanates. Because there was no EPA test method for isocyanate emissions, as part of this action, we are finalizing specific isocyanate compound sample collection and analytical requirements as EPA Method 326 of 40 CFR part 63, appendix A. EPA Method 326 is based on ''A Method for Measuring Isocyanates in Stationary Source Emissions,'' which was proposed on December 8, 1997 (see 62 FR 64532) as EPA Method 207, but was never promulgated. EPA Method 326 does not significantly modify the sampling and analytical techniques of the previously proposed method, but includes additional QC procedures and associated performance criteria to ensure the overall quality of the measurement.

EPA Method 326 is based on the EPA Method 5 sampling train employing a derivatizing reagent (1-(2-pyridyl) piperazine in toluene) in the impingers to immediately stabilize the isocyanate compounds upon collection. Collected samples are analyzed using high performance liquid chromatography and an appropriate detector under laboratory conditions sufficient to separate and quantify the isocyanate compounds.

The sampling and analytical techniques were validated at three sources according to EPA Method 301 (40 CFR part 63, appendix A) and the report of this validation, titled *Laboratory Development and Field Evaluation of a Generic Method for Sampling and Analysis of Isocyanates,* can be found in the docket, Docket ID No. EPA–HQ–OAR–2016–0678. Under the final rule, this validated technique would be used to reliably collect and analyze gaseous isocyanate emissions from surface coatings of wood building products for methylene diphenyl diisocyanate (MDI), methyl isocyanate (MI), hexamethylene-1,6-diisocyanate (HDI), and 2,4 toluene diisocyanate (TDI). This method will also provide a tool for state and local governments,

industry, and the EPA to reliably measure emissions of MDI, MI, HDI, and/or TDI from other types of stationary sources, such as pressed board, flexible foam, and spray booths.

H. IBR Under 1 CFR Part 51

The EPA is finalizing regulatory text that includes IBR. In accordance with requirements of 1 CFR 51.5, the EPA is incorporating by reference National Council of the Paper Industry for Air and Stream Improvement, Inc. (NCASI) Method ISS/FP A105.01 and the following voluntary consensus standards (VCS) described in the amendments to 40 CFR 63.14:

- ANSI A135.4–2012, Basic Hardboard, approved June 8, 2012, IBR approved for 40 CFR 63.4781.
- ASTM D1475–13, Standard Test Method for Density of Liquid Coatings, Inks, and Related Products, approved November 1, 2013, IBR approved for 40 CFR 63.4741(b)(3) and (c) and 63.4751(c).
- ASTM D2111–10 (Reapproved 2015), Standard Test Methods for Specific Gravity and Density of Halogenated Organic Solvents and Their Admixtures, approved June 1, 2015, IBR approved for 40 CFR 63.4741(a)(2)(i).
- ASTM D2369–10 (Reapproved 2015) [e], Standard Test Method for Volatile Content of Coatings, approved June 1, 2015, IBR approved for 40 CFR 63.4741(a)(2)(ii).
- ASTM D2697–03 (Reapproved 2014), Standard Test Method for Volume Nonvolatile Matter in Clear or Pigmented Coatings, approved July 1, 2014, IBR approved for 40 CFR 63.4741(a)(2)(iii) and (b).
- ASTM D4840–99 (Reapproved 2018) [e], Standard Guide for Sampling Chain-of-Custody Procedures, approved August 15, 2018, IBR approved for EPA Method 326 in appendix A to part 63.
- ASTM D6093–97 (Reapproved 2016), Standard Test Method for Percent Volume Nonvolatile Matter in Clear or Pigmented Coatings Using a Helium Gas Pycnometer, Approved December 1, 2016, IBR approved for 40 CFR 63.4741(a)(2)(iv) and (b)(1).
- ASTM D6348–03 (Reapproved 2010), Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, including Annexes A1 through A8, Approved October 1, 2010, IBR approved for 40 CFR 63.4751(i) introductory paragraph and (i)(4), 63.4752(e), and 63.4766(b) introductory paragraph and (b)(4).

While the American Society for Testing and Materials (ASTM) methods D2697–86 and D6093–97 were incorporated by reference when 40 CFR part 63, subpart QQQQ, was originally promulgated (68 FR 31760), the methods have been updated and reapproved and are also being cited in additional paragraphs in the final rule, requiring a revision to their IBR. NCASI Method ISS/FP A105.01 was incorporated by reference when 40 CFR part 63, subpart DDDD, Table 4 was amended in 2006. The American National Standards Institute (ANSI) method (published by the Composite Panel Association) and the other ASTM methods are being incorporated by reference for 40 CFR part 63, subpart QQQQ, for the first time under this rulemaking.

I. Technical and Editorial Changes

The following are additional final changes that address technical and editorial corrections:

- Revised the monitoring requirements section in 40 CFR 63.4764 to clarify ongoing compliance provisions to address startup and shutdown periods when certain parameters cannot be met;
- Revised the recordkeeping requirements section in 40 CFR 63.4730 to include the requirement to record information on failures to meet the applicable standard;
- Revised the references to several test method appendices;
- Revised the General Provisions applicability table (Table 4 to Subpart QQQQ of Part 63) to align with sections of the General Provisions that have been amended or reserved over time; and
- Revised 40 CFR 63.4681 to update reference to 40 CFR part 63, subpart DDDD.

V. Summary of Cost, Environmental, and Economic Impacts and Additional Analyses Conducted

A. What are the affected facilities?

There are currently 57 wood building product manufacturing facilities operating in the United States that conduct surface coating operations and are subject to the Surface Coating of Wood Building Products NESHAP. The 40 CFR part 63, subpart QQQQ, affected source is the collection of all the items listed in 40 CFR 63.4682(b)(1) through (4) that are used for surface coating of wood building products. A new affected source is a completely new wood building products surface coating source where previously no wood building products surface coating source had existed.

B. What are the air quality impacts?

At the current level of control, the EPA estimates emissions of total HAP are approximately 270 tpy.[5] Compared to pre-MACT levels, this represents a significant reduction of HAP for the category. Prior to the development of the Surface Coating of Wood Building Products NESHAP, the EPA estimated HAP emissions to be 14,300 tons annually.[6] The final amendments will require all 57 major sources with equipment subject to the Wood Building Products Coating NESHAP to operate without the SSM exemption. We are unable to quantify the specific emissions reductions associated with eliminating the SSM exemption, but eliminating the SSM exemption will reduce emissions by requiring facilities to meet the applicable standard during SSM periods.

Indirect or secondary air emissions impacts are impacts that would result from the increased electricity usage associated with the operation of control devices (*i.e.,* increased secondary emissions of criteria pollutants from power plants). Energy impacts consist of the electricity and steam needed to operate control devices and other equipment that would be required under this rule. The EPA expects no secondary air emissions impacts or energy impacts from this rulemaking because this action does not amend the numeric emission limit.

For further information, see the memoranda titled *Cost Impacts of the Subpart QQQQ Residual Risk and Technology Review* and *Economic Impact and Small Business Screening Assessments for Final Amendments to the National Emission Standards for Hazardous Air Pollutants: Surface Coating of Wood Building Products,* in the docket for this action, Docket ID No. EPA–HQ–OAR–2016–0678.

C. What are the cost impacts?

We estimate that, as a result of these final amendments, each facility in the source category will experience reporting and recordkeeping costs. Each facility will experience costs to read and understand the rule amendments. Costs associated with the elimination of the SSM exemption were estimated as part of the reporting and recordkeeping costs and include time for re-evaluating previously developed SSM record systems. Costs associated with the requirement to electronically submit

[5] For more information, see the memorandum in the docket titled, *Addendum to Preparation of the Residual Risk Modeling Input File for Subpart QQQQ;* Docket ID No. EPA–HQ–OAR–2016–0678.

[6] *National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Wood Building Products (Surface Coating) Industry—Background Information for Proposed Standards;* EPA–453/R–00–003; May 2001.

notifications and semiannual compliance reports using CEDRI were estimated as part of the reporting and recordkeeping costs and include time for becoming familiar with CEDRI and the reporting template for semiannual compliance reports. The reporting and recordkeeping costs are presented in this section of the preamble. A thorough discussion of the facility-by-facility costs is contained in the supporting statement for the 40 CFR part 63, subpart QQQQ amendments, *Supporting Statement, NESHAP for the Wood Building Products Surface Coating Industry (40 CFR part 63, subpart QQQQ) (Final Amendments); December 2018,* which can be found in the docket for this rule, Docket ID No. EPA–HQ–OAR–2016–0678.

The EPA estimates that one facility will be impacted by this final regulatory action. This facility will conduct an initial performance test to demonstrate compliance with the alternative compliance equation, as related to their request for an alternative monitoring method. This initial performance test has a cost of $22,000, and the repeat testing will cost $22,000 every 5 years.

The total estimated labor costs for the rule are summarized in the Supporting Statement for the information collection request (ICR) in the docket for this action. The estimated labor cost is $38,000 for all 57 affected facilities to become familiar with the final rule requirements. For further information, see the memorandum titled *Cost Impacts of the Subpart QQQQ Residual Risk and Technology Review,* in the docket for this action, Docket ID No. EPA–HQ–OAR–2016–0678.

D. What are the economic impacts?

Economic impact analyses focus on changes in market prices and output levels. If changes in market prices and output levels in the primary markets are significant enough, impacts on other markets may also be examined. Both the magnitude of costs needed to comply with a final rule and the distribution of these costs among affected facilities can have a role in determining how the market will change in response to a final rule.

For the one facility expected to conduct an initial performance test and become familiar with the final rule requirements, the costs associated with 40 CFR part 63, subpart QQQQ's final requirements are approximately 0.002 percent of annual sales revenues. For the remaining 56 facilities, the costs associated with becoming familiar with the final rule requirements are less than 0.001 percent of annual sales revenues. These costs are not expected to result in a significant market impact, regardless of whether they are passed on to the purchaser or absorbed by the firms. For further information, see the memorandum titled *Economic Impact and Small Business Screening Assessments for Final Amendments to the National Emission Standards for Hazardous Air Pollutants: Surface Coating of Wood Building Products,* in the docket for this action, Docket ID No. EPA–HQ–OAR–2016–0678.

E. What are the benefits?

The EPA did not change any of the emission limit requirements and estimates the final changes to SSM, recordkeeping, reporting, and monitoring are not economically significant. Because these final amendments are not considered economically significant, as defined by Executive Order 12866, and because no emission reductions were estimated, we did not estimate any benefits from reducing emissions.

F. What analysis of environmental justice did we conduct?

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on EJ. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make EJ part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

To examine the potential for any EJ issues that might be associated with the source category, we performed a demographic analysis, which is an assessment of risks to individual demographic groups of the populations living within 5 kilometers (km) and within 50 km of the facilities. In the analysis, we evaluated the distribution of HAP-related cancer and noncancer risks from the Surface Coating of Wood Building Products source category across different demographic groups within the populations living near facilities.[7]

The results of the demographic analysis are summarized in Table 3 below. These results for various demographic groups are based on the estimated risks from actual emissions levels for the population living within 50 km of the facilities.

TABLE 3—SURFACE COATING OF WOOD BUILDING PRODUCTS SOURCE CATEGORY DEMOGRAPHIC RISK ANALYSIS RESULTS

	Nationwide	Population with cancer risk at or above 1-in-1 million due to wood building products surface coating [1]	Population with chronic HI above 1 due to wood building products surface coating
Total Population	317,746,049	0	0
Race by Percent			
White	62	0	0
All Other Races	38	0	0
Race by Percent			
White	62	0	0
African American	12	0	0
Native American	0.8	0	0

[7] Demographic groups included in the analysis are: White, African American, Native American, other races, and multiracial, Hispanic or Latino, children 17 years of age and under, adults 18 to 64 years of age, adults 65 years of age and over, adults without a high school diploma, people living below the poverty level, people living two times the poverty level, and linguistically isolated people.

TABLE 3—SURFACE COATING OF WOOD BUILDING PRODUCTS SOURCE CATEGORY DEMOGRAPHIC RISK ANALYSIS RESULTS—Continued

	Nationwide	Population with cancer risk at or above 1-in-1 million due to wood building products surface coating [1]	Population with chronic HI above 1 due to wood building products surface coating
Other and Multiracial	7	0	0
Ethnicity by Percent			
Hispanic	18	0	0
Non-Hispanic	82	0	0
Income by Percent			
Below Poverty Level	14	0	0
Above Poverty Level	86	0	0
Education by Percent			
Over 25 and without High School Diploma	14	0	0
Over 25 and with a High School Diploma	86	0	0
Linguistically Isolated by Percent			
Linguistically Isolated	6%	0%	0%

[1] Based on actual emissions in the category.

The results of the Surface Coating of Wood Building Products source category demographic analysis indicate that emissions from the source category do not expose people to a cancer risk at or above 1-in-1 million based on actual emissions. Also, no people are exposed to a chronic noncancer TOSHI greater than 1. The percentages of the at-risk population are demographically similar to their respective nationwide percentages for all demographic groups.

The EPA received a comment on our proposed rule stating that we ignored unacceptably disproportionate effects on EJ communities. As noted above, we re-evaluated our risk impacts from the category with a revised risk assessment. One aspect of this assessment was that it generated a risk report based on a more refined risk assessment model. Those risk model results did show lower risk in the EJ communities where larger impacts were noted at proposal. The EPA considered this comment and has reaffirmed its determination that this final rule will not have disproportionately high and adverse human health or environmental effects on minority, low income, or indigenous populations because it increases the level of environmental protection for all affected populations.

The methodology and the results of the demographic analysis are presented in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Surface Coating of Wood Building Products Source Category Operations,* available in the docket for this action, EPA–HQ–OAR–2016–0678.

G. What analysis of children's environmental health did we conduct?

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in *Residual Risk Assessment for the Surface Coating of Wood Building Products Source Category in Support of the 2018 Risk and Technology Review Final Rule,* available in the docket for this action, Docket ID No. EPA–HQ–OAR–2016–0678.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Orders 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for approval to OMB under the PRA. The ICR document that the EPA prepared has been assigned EPA ICR number 2034.08. You can find a copy of the ICR in the docket for this rule (Docket ID No. EPA–HQ–OAR–2016–0678), and it is briefly summarized here.

We are finalizing changes to the paperwork requirements for the Surface Coating of Wood Building Products NESHAP in the form of eliminating the SSM reporting and SSM plan requirements, and requiring electronic submittal of semiannual compliance reports and any future notifications of compliance status or performance test reports.

Respondents/affected entities: Respondents include wood building product manufacturing facilities with surface coating operations subject to the Surface Coating of Wood Building Products NESHAP.

Respondent's obligation to respond: Mandatory (authorized by section 114 of the CAA).

Estimated number of respondents: 57.

Frequency of response: The frequency of responses varies depending on the burden item. Responses include notifications, reports of performance tests, and semiannual compliance reports.

Total estimated burden: The annual recordkeeping and reporting burden for this information collection, averaged over the first 3 years of this ICR, is estimated to total 20,208 labor hours per year. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,465,000 per year in labor costs, including $38,000 in labor cost for all 57 facilities to become familiar with the final rule requirements. An additional cost of $22,000 is estimated for an initial performance test at one facility during the 3-year ICR period. These estimated costs represent the full ongoing information collection burden for 40 CFR part 63, subpart QQQQ, as revised by the final amendments being promulgated.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. In addition, the EPA is amending the table in 40 CFR part 9 to list the regulatory citations for the information collection activities contained in this final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. We conducted an economic impact analysis which is available in the docket for this final rule, Docket ID No. EPA–HQ–OAR–2016–0678. For all but one of the facilities affected by the final rule, including the small businesses, the costs associated with the final rule requirements are less than 0.001 percent of annual sales revenues; for the remaining facility, the costs are less than 0.002 percent of annual sales revenues. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian Tribes, or on the distribution of power and responsibilities between the federal government and Indian Tribes, as specified in Executive Order 13175. This final rule imposes requirements on owners and operators of wood building product surface coating facilities and not tribal governments. The EPA discussed the proposed action at a meeting of the National Tribal Air Association,[8] and has not been informed and does not know of any wood building product surface coating facilities owned or operated by Indian tribal governments. However, if there are any, the effect of this rule on communities of tribal governments would not be unique or disproportionate to the effect on other communities. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. A description of the health risk assessment conducted as part of this action is provided in sections III and IV of this preamble and further documented in the risk report titled *Residual Risk Assessment for the Surface Coating of Wood Building Products Source Category in Support of the 2018 Risk and Technology Review Final Rule,* in the docket for this action, Docket ID No. EPA–HQ–OAR–2016–0678.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards. The EPA is finalizing the use of NCASI Method ISS/FP A105.01, ''Impinger Source Sampling Method for Selected Aldehydes, Ketones, and Polar Compounds,'' December 2005, Methods Manual, and ASTM D6348–03 (Reapproved 2010), ''Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy'' as alternatives to using EPA Method 320 under certain conditions, and is incorporating these alternative methods by reference. EPA Method 320 is added for the measurement of organic HAP emissions if formaldehyde is a major organic HAP component of the surface coating exhaust stream. EPA Method 320 can also be used for other HAP that may be found in wood building products coatings. NCASI Method ISS/FP A105.01 is an impinger source sampling method for the collection and analysis of a wider range of aldehydes, ketones, and polar organics, has previously been incorporated by reference at 40 CFR 63.14, and is reasonably available from National Council of the Paper Industry for Air and Stream Improvement, Inc. (NCASI), P.O. Box 133318, Research Triangle Park, NC 27709–3318 or at *http://www.ncasi.org.*

Instead of the current ASTM D6348–12 standard, the ASTM D6348–03 (Reapproved 2010) standard is referenced in the Surface Coating of Wood Building Products NESHAP. The QC criteria in ASTM D6348–03 (Reapproved 2010) are more closely matched to the testing requirements in this NESHAP. Use of ASTM D6348–03 (Reapproved 2010) is defined in 40 CFR 63.4751(i)(4). ASTM D6348–03 (Reapproved 2010) is an extractive FTIR

[8] See *National Tribal Air Association—EPA Air Policy Update Call;* Thursday May 31, 2018, in the docket for this rule; Docket ID No. EPA–HQ–OAR–2016–0678.

spectroscopy-based field test method and is used to quantify gas phase concentrations of multiple target compounds in emission streams from stationary sources.

ANSI A135.4–2012, ''Basic Hardboard,'' is reasonably available from the Composite Panel Association, 19465 Deerfield Avenue, Suite 306, Leesburg, VA 20176. The standard specifies requirements and test methods for water absorption, thickness swelling, modulus of rupture, tensile strength, surface finish, dimensions, squareness, edge straightness, and moisture content for five classes of hardboard, including tileboard, part of a subcategory in the standard.

The EPA is also using ASTM D4840–99 (Reapproved 2018)[e], ''Standard Guide for Sampling Chain-of-Custody Procedures,'' in EPA Method 326 for its chain of custody procedures and is incorporating this alternative method by reference. The ASTM D4840–99 (Reapproved 2018)[e] guide contains a comprehensive discussion of potential requirements for a sample chain-of-custody program and describes the procedures involved in sample chain-of-custody. The purpose of ASTM D4840–99 (Reapproved 2018)[e] procedures is to provide accountability for and documentation of sample integrity from the time samples are collected until the time samples are disposed. EPA Method 326 is added for the measurement of organic HAP emissions if isocyanate is a major organic HAP component of the surface coating exhaust stream.

The EPA is finalizing the use of the following four VCS as alternatives to EPA Method 24 for the determination of volatile matter content, water content, density, volume solids, and weight solids of surface coatings and incorporate these VCS by reference:

- ASTM D2111–10 (Reapproved 2015), ''Standard Test Methods for Specific Gravity of Halogenated Organic Solvents and Their Admixtures.'' These test methods are used for the determination of the specific gravity of halogenated organic solvents and solvent admixtures.
- ASTM D2369–10 (Reapproved 2015)[e], ''Standard Test Method for Volatile Content of Coatings.'' This test method describes a procedure used for the determination of the weight percent volatile content of solvent-borne and waterborne coatings.
- ASTM D2697–03 (Reapproved 2014), ''Standard Test Method for Volume Nonvolatile Matter in Clear or Pigmented Coatings.'' This test method is applicable to the determination of the volume of nonvolatile matter in coatings.
- ASTM D6093–97 (Reapproved 2016), ''Standard Test Method for Percent Volume Nonvolatile Matter in Clear or Pigmented Coatings Using a Helium Gas Pycnometer.'' This test method is used for the determination of the percent volume nonvolatile matter in clear and pigmented coatings.

The ASTM standards are reasonably available from the American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, Post Office Box C700, West Conshohocken, PA 19428–2959. See *http://www.astm.org/.*

While the EPA has identified another 18 VCS as being potentially applicable to this final rule, we have decided not to use these VCS in this rulemaking. The use of these VCS would not be practical due to lack of equivalency, documentation, validation date, and other important technical and policy considerations. See the memorandum titled *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants: Surface Coating of Wood Building Products,* in the docket for this final rule for the reasons for these determinations.

Under 40 CFR 63.7(f) and 40 CFR 63.8(f) of subpart A of the General Provisions, a source may apply to the EPA for permission to use alternative test methods or alternative monitoring requirements in place of any required testing methods, performance specifications, or procedures in the final rule or any amendments.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in section IV.A of this preamble and the technical report titled *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Wood Building Products Surface Coating Sources,* which is located in the public docket for this action, Docket ID No. EPA–HQ–OAR–2016–0678.

We examined the potential for any EJ issues that might be associated with the source category by performing a demographic analysis of the population close to the facilities. See section V.F, above. In this analysis, we evaluated the distribution of HAP-related cancer and noncancer risks from the Surface Coating of Wood Building Products NESHAP source category across different social, demographic, and economic groups within the populations living near facilities identified as having the highest risks. The methodology and the results of the demographic analyses are included in a technical report, *Risk and Technology Review—Analysis of Demographic Factors for Populations Living Near Surface Coating of Wood Building Products Source Category Operations,* available in the docket for this action, Docket ID No. EPA–HQ–OAR–2016–0678.

The results of the Surface Coating of Wood Building Products NESHAP source category demographic analysis indicate that approximately 700 people may be exposed to a cancer risk of 1-in-1 million based on allowable emissions from the source category and no one is exposed to a chronic noncancer TOSHI greater than 1. The specific demographic results indicate that the percentage of the population potentially impacted by wood building products emissions is similar among all demographic groups (see Table 3 of this preamble). The proximity results (irrespective of risk) indicate that the population percentages for certain demographic categories within 5 km of source category emissions are greater than the corresponding national percentage for those same demographics. The following demographic percentages for populations residing within close proximity to facilities with Surface Coating of Wood Building Products source category facilities are higher than the corresponding nationwide percentage: African American, ages 65 and up, over age 25 without a high school diploma, and below the poverty level.

The risks due to actual HAP emissions from this source category are low for all populations (*e.g.,* inhalation cancer risks are less than 1-in-1 million for all populations and noncancer HIs are less than 1). We do not expect this final rule to achieve significant reductions in HAP emissions. We have concluded that this final rule will not have unacceptable adverse human health or environmental effects on minority or low-income populations. The final rule does not affect the level of protection provided to human health or the environment. However, this final rule will provide additional benefits to these demographic groups by improving the compliance, monitoring, and implementation of the NESHAP.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to

each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Incorporation by reference, National Emission Standards for Hazardous Air Pollutants: Surface Coating of Wood Building Products Residual Risk and Technology Review, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: December 20, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart A—[Amended]

■ 2. Section 63.14 is amended:

■ a. In paragraph (a), by removing—''*http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*'' and adding ''*www.archives.gov/federal-register/cfr/ibr-locations.html*'' in its place;

■ b. By redesignating the paragraphs in the Old Paragraph column as the paragraphs in the New Paragraph column as follows:

Old paragraph	New paragraph
(c)	(f)
(d)	(g)
(e) through (g)	(c) through (e)
(l) through (s)	(m) through (t);

■ c. In paragraph (h)—

■ i. In the introductory text, by removing ''American Society for Testing and Materials (ASTM)'' and adding ''ASTM International'' in its place;

■ ii. By redesignating the paragraphs in the Old Paragraph column as the paragraphs in the New Paragraph column as follows:

Old paragraph	New paragraph
(h)(13) through (h)(19)	(h)(14) through (h)(20)
(h)(20) through (h)(23)	(h)(22) through (h)(25)
(h)(24) through (h)(26)	(h)(27) through (h)(29)
(h)(27) through (h)(59)	(h)(31) through (h)(63)
(h)(60) through (h)(73)	(h)(65) through (h)(78)
(h)(74) through (h)(105) ..	(h)(80) through (h)(111);

■ iii. By adding new paragraphs (h)(13), (21), (26), (30), (64), and (79); and

■ iv. By revising newly redesignated paragraph (h)(84).

■ d. By adding new paragraph (l); and

■ e. By revising newly designated paragraph (p)(5).

The revisions and additions read as follows:

§ 63.14 Incorporations by reference.

* * * * *

(h) * * *

(13) ASTM D1475–13, Standard Test Method for Density of Liquid Coatings, Inks, and Related Products, approved November 1, 2013, IBR approved for §§ 63.4741(b) and (c) and 63.4751(c).

* * * * *

(21) ASTM D2111–10 (Reapproved 2015), Standard Test Methods for Specific Gravity and Density of Halogenated Organic Solvents and Their Admixtures, approved June 1, 2015, IBR approved for § 63.4741(a).

* * * * *

(26) ASTM D2369–10 (Reapproved 2015)[e], Standard Test Method for Volatile Content of Coatings, approved June 1, 2015, IBR approved for § 63.4741(a).

* * * * *

(30) ASTM D2697–03 (Reapproved 2014), Standard Test Method for Volume Nonvolatile Matter in Clear or Pigmented Coatings, approved July 1, 2014, IBR approved for § 63.4741(a) and (b).

* * * * *

(64) ASTM D4840–99 (Reapproved 2018)[e], Standard Guide for Sampling Chain-of-Custody Procedures, approved August 15, 2018, IBR approved for appendix A to part 63.

* * * * *

(79) ASTM D6093–97 (Reapproved 2016), Standard Test Method for Percent Volume Nonvolatile Matter in Clear or Pigmented Coatings Using a Helium Gas Pycnometer, Approved December 1, 2016, IBR approved for § 63.4741(a) and (b).

* * * * *

(84) ASTM D6348–03 (Reapproved 2010), Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, including Annexes A1 through A8, Approved October 1, 2010, IBR approved for §§ 63.1571(a), 63.4751(i), 63.4752(e), 63.4766(b), tables 4 and 5 to subpart JJJJJ, tables 4 and 6 to subpart KKKKK, tables 1, 2, and 5 to subpart UUUUU and appendix B to subpart UUUUU.

* * * * *

(l) Composite Panel Association, 19465 Deerfield Avenue, Suite 306, Leesburg, VA 20176, Telephone (703)724–1128, and *www.compositepanel.org.*

(1) ANSI A135.4–2012, Basic Hardboard, approved June 8, 2012, IBR approved for § 63.4781.

(2) [Reserved]

* * * * *

(p) * * *

(5) NCASI Method ISS/FP A105.01, Impinger Source Sampling Method for Selected Aldehydes, Ketones, and Polar Compounds, December 2005, Methods Manual, IBR approved for table 4 to subpart DDDD and §§ 63.4751(i) and 63.4752(e).

* * * * *

Subpart QQQQ—[Amended]

■ 4. Section 63.4681 is amended by revising paragraph (c)(1) introductory text to read as follows:

§ 63.4681 Am I subject to this subpart?

* * * * *

(c) * * *

(1) Surface coating in the processes identified in paragraphs (c)(1)(i) through (xi) of this section that are part of plywood and composite wood product manufacturing and subject to subpart DDDD of this part including:

* * * * *

■ 5. Section 63.4683 is amended by revising paragraphs (a) and (b) to read as follows:

§ 63.4683 When do I have to comply with this subpart?

* * * * *

(a) For a new or reconstructed affected source, the compliance date is the applicable date in paragraph (a)(1) or (2) of this section:

(1) If the initial startup of your new or reconstructed affected source is before May 28, 2003, the compliance date is May 28, 2003; except that the compliance date for the revised requirements promulgated at §§ 63.4700, 63.4710, 63.4720, 63.4730, 63.4741, 63.4751, 63.4752, 63.4761, 63.4763, 63.4764, 63.4766, 63.4781, table 4 of this subpart QQQQ, and appendix A to 40 CFR part 63 is September 3, 2019.

(2) If the initial startup of your new or reconstructed affected source occurs after May 28, 2003, the compliance date is March 4, 2019 or the date of initial startup of your affected source, whichever is later; except that if you commenced construction or reconstruction of your new or reconstructed affected source after May 28, 2003, but on or before May 16, 2018, the compliance date for the revised requirements promulgated at

§§ 63.4700, 63.4710, 63.4720, 63.4730, 63.4741, 63.4751, 63.4752, 63.4761, 63.4763, 63.4764, 63.4766, 63.4781, table 4 of this subpart QQQQ, and appendix A to 40 CFR part 63 is September 3, 2019.

(b) For an existing affected source, the compliance date is the date 3 years after May 28, 2003, except that the compliance date for the revised requirements promulgated at §§ 63.4700, 63.4710, 63.4720, 63.4730, 63.4741, 63.4751, 63.4752, 63.4761, 63.4763, 63.4764, 63.4766, 63.4781, table 4 of this subpart QQQQ of part 63, and appendix A to 40 CFR part 63 is September 3, 2019.

* * * * *

■ 6. Section 63.4700 is amended by:
■ a. Revising paragraph (a)(2) introductory text and paragraphs (a)(2)(i) and (ii);
■ b. Adding paragraph (a)(3); and
■ c. Revising paragraphs (b) and (d).

The revisions and addition read as follows:

§ 63.4700 What are my general requirements for complying with this subpart?

(a) * * *

(2) Any coating operation(s) at existing sources for which you use the emission rate with add-on controls option, as specified in § 63.4691(c), must be in compliance with the applicable emission limitations as specified in paragraphs (a)(2)(i) through (iii) of this section.

(i) Before September 3, 2019, the coating operation(s) must be in compliance with the applicable emission limit in § 63.4690 at all times, except during periods of startup, shutdown, and malfunction (SSM). On and after September 3, 2019, the coating operation(s) must be in compliance with the applicable emission limit in § 63.4690 at all times.

(ii) Before September 3, 2019, the coating operation(s) must be in compliance with the applicable operating limits for emission capture systems and add-on control devices required by § 63.4692 at all times, except during periods of SSM, and except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4761(j). On and after September 3, 2019, the coating operation(s) must be in compliance with the operating limits for emission capture systems and add-on control devices required by § 63.4692 at all times, except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4761(j).

* * * * *

(3) For new or reconstructed sources with initial startup after May 16, 2018, any coating operation(s) for which you use the emission rate with add-on controls option, as specified in § 63.4691(c), must be in compliance with the applicable emission limitations and work practice standards as specified in paragraphs (a)(3)(i) through (iii) of this section.

(i) The coating operation(s) must be in compliance with the applicable emission limit in § 63.4690 at all times.

(ii) The coating operation(s) must be in compliance with the operating limits for emission capture systems and add-on control devices required by § 63.4692 at all times, except for solvent recovery systems for which you conduct liquid-liquid material balances according to § 63.4761(j).

(iii) The coating operation(s) must be in compliance with the work practice standards in § 63.4693 at all times.

(b) For existing sources as of March 4, 2019, before September 3, 2019, you must always operate and maintain your affected source, including all air pollution control and monitoring equipment you use for purposes of complying with this subpart, according to the provisions in § 63.6(e)(1)(i). On and after September 3, 2019 for such existing sources and after March 4, 2019 for new or reconstructed sources, you must always operate and maintain your affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. The general duty to minimize emissions does not require you to make any further efforts to reduce emissions if levels required by the applicable standard have been achieved. Determination of whether a source is operating in compliance with operation and maintenance requirements will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

* * * * *

(d) For existing sources, before September 3, 2019, if your affected source uses an emission capture system and add-on control device, you must develop a written startup, shutdown, and malfunction plan (SSMP) according to the provisions in § 63.6(e)(3). The SSMP must address startup, shutdown, and corrective actions in the event of a malfunction of the emission capture system or the add-on control device. The SSMP must also address any coating operation equipment that may cause increased emissions or that would affect capture efficiency if the process equipment malfunctions, such as conveyors that move parts among enclosures.

■ 7. Section 63.4710 is amended by revising paragraph (c)(8)(ii) to read as follows:

§ 63.4710 What notifications must I submit?

* * * * *

(c) * * *

(8) * * *

(ii) For the emission rate without add-on controls option, provide the calculation of the total mass of organic HAP emissions for each month; the calculation of the total volume of coating solids used each month; and the calculation of the 12-month organic HAP emission rate, using Equations 1 and 1A (or 1A-alt) through 1C, 2, and 3, respectively, of § 63.4751.

* * * * *

■ 8. Section 63.4720 is amended by:
■ a. Revising paragraph (a)(6)(ii) and paragraph (a)(7) introductory text;
■ b. Redesignating paragraphs (a)(7)(i) through (xiv) as paragraphs (a)(7)(i)(A) through (N);
■ c. Adding paragraph (a)(7)(i) introductory text and paragraph (a)(7)(ii);
■ d. Revising paragraph (c) introductory text; and
■ e. Adding paragraph (d).

The revisions and additions read as follows:

§ 63.4720 What reports must I submit?

(a) * * *

(6) * * *

(ii) The calculations used to determine the 12-month organic HAP emission rate for the compliance period in which the deviation occurred. You must provide the calculations for Equations 1, 1A (or 1A-alt) through 1C, 2, and 3 in § 63.4751; and if applicable, the calculation used to determine mass of organic HAP in waste materials according to § 63.4751(e)(4). You do not need to submit background data supporting these calculations (*e.g.,* information provided by materials suppliers or manufacturers, or test reports).

* * * * *

(7) *Deviations: Emission rate with add-on controls option.* You must be in compliance with the emission limitations in this subpart as specified in paragraphs (a)(7)(i) and (ii) of this section.

(i) For existing sources, before September 3, 2019, if you used the emission rate with add-on controls option and there was a deviation from an emission limitation (including any periods when emissions bypassed the add-on control device and were diverted to the atmosphere), the semiannual compliance report must contain the information in paragraphs (a)(7)(i)(A) through (N) of this section. This includes periods of SSM during which deviations occurred.

* * * * *

(ii) After March 4, 2019 for new and reconstructed sources, and on and after September 3, 2019 for existing sources, if you used the emission rate with add-on controls option and there was a deviation from an emission limitation (including any periods when emissions bypassed the add-on control device and were diverted to the atmosphere), the semiannual compliance report must contain the information in paragraphs (a)(7)(ii)(A) through (M) of this section.

(A) The beginning and ending dates of each compliance period during which the 12-month organic HAP emission rate exceeded the applicable emission limit in § 63.4690.

(B) The calculations used to determine the 12-month organic HAP emission rate for each compliance period in which a deviation occurred. You must provide the calculation of the total mass of organic HAP emissions for the coatings, thinners, and cleaning materials used each month, using Equations 1 and 1A through 1C of § 63.4751; and, if applicable, the calculation used to determine mass of organic HAP in waste materials according to § 63.4751(e)(4); the calculation of the total volume of coating solids used each month, using Equation 2 of § 63.4751; the calculation of the mass of organic HAP emission reduction each month by emission capture systems and add-on control devices, using Equations 1 and 1A through 1D of § 63.4761, and Equations 2, 3, and 3A through 3C of § 63.4761, as applicable; the calculation of the total mass of organic HAP emissions each month, using Equation 4 of § 63.4761; and the calculation of the 12-month organic HAP emission rate, using Equation 5 of § 63.4761. You do not need to submit the background data supporting these calculations (*e.g.,* information provided by materials suppliers or manufacturers, or test reports).

(C) A brief description of the CPMS.

(D) The date of the latest CPMS certification or audit.

(E) The date and time that each CPMS was inoperative, except for zero (low-level) and high-level checks.

(F) The date, time, and duration that each CPMS was out-of-control, including the information in § 63.8(c)(8).

(G) The date and time period of each deviation from an operating limit in Table 3 to this subpart, date and time period of any bypass of the add-on control device.

(H) A summary of the total duration of each deviation from an operating limit in Table 3 to this subpart, each bypass of the add-on control device during the semiannual reporting period, and the total duration as a percent of the total source operating time during that semiannual reporting period.

(I) A breakdown of the total duration of the deviations from the operating limits in Table 3 to this subpart and bypasses of the add-on control device during the semiannual reporting period by identifying deviations due to control equipment problems, process problems, other known causes, and other unknown causes; a list of the affected source or equipment, an estimate of the quantity of each regulated pollutant emitted over any emission limit, and a description of the method used to estimate the emissions.

(J) A summary of the total duration of CPMS downtime during the semiannual reporting period and the total duration of CPMS downtime as a percent of the total source operating time during that semiannual reporting period.

(K) A description of any changes in the CPMS, coating operation, emission capture system, or add-on control device since the last semiannual reporting period.

(L) For each deviation from the standard, including work practice standards, a description of the deviation, the date and time period of the deviation, and the actions you took to correct the deviation.

(M) A statement of the cause of each deviation.

* * * * *

(c) *SSM reports.* For existing sources, before September 3, 2019, if you used the emission rate with add-on controls option and you had an SSM during the semiannual reporting period, you must submit the reports specified in paragraphs (c)(1) and (2) of this section.

* * * * *

(d) *Electronic reporting.* (1) Within 60 days after the date of completing each performance test required by this subpart, you must submit the results of the performance test following the procedures specified in paragraphs (d)(1)(i) through (iii) of this section.

(i) *Data collected using test methods supported by EPA's Electronic Reporting Tool (ERT) as listed on EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test.* Submit the results of the performance test to the EPA via the Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). The data must be submitted in a file format generated through the use of EPA's ERT. Alternatively, you may submit an electronic file consistent with the extensible markup language (XML) schema listed on EPA's ERT website.

(ii) *Data collected using test methods that are not supported by EPA's ERT as listed on EPA's ERT website at the time of the test.* The results of the performance test must be included as an attachment in the ERT or an alternate electronic file consistent with the XML schema listed on EPA's ERT website. Submit the ERT generated package or alternative file to the EPA via CEDRI.

(iii) *Confidential business information (CBI).* If you claim some of the information submitted under paragraph (a)(1) of this section is CBI, you must submit a complete file, including information claimed to be CBI, to the EPA. The file must be generated through the use of EPA's ERT or an alternate electronic file consistent with the XML schema listed on EPA's ERT website. Submit the file on a compact disc, flash drive, or other commonly used electronic storage medium and clearly mark the medium as CBI. Mail the electronic medium to U.S. EPA/OAQPS/CORE CBI Office, Attention: Group Leader, Measurement Policy Group, MD C404–02, 4930 Old Page Rd., Durham, NC 27703. The same file with the CBI omitted must be submitted to the EPA via EPA's CDX as described in paragraph (d)(1)(i) of this section.

(2) You must submit the Notification of Compliance Status required in § 63.4710(c) and the semiannual compliance reports required in paragraph (a) of this section to the EPA via the CEDRI. (CEDRI can be accessed through the EPA's CDX (*https://cdx.epa.gov/*)). For semiannual compliance reports, you must use the appropriate electronic report in CEDRI for this subpart or an alternative electronic file format consistent with the XML schema listed on the CEDRI website (*https://www.epa.gov/electronic-reporting-air-emissions/compliance-and-emissions-data-reporting-interface-cedri*). If the reporting form specific to this subpart is not available in CEDRI at the time that

the report is due, you must submit the report to the Administrator at all the appropriate addresses listed in § 63.13. Once the reporting template has been available in CEDRI for 1 year, you must begin submitting all subsequent reports via CEDRI. For the Notification of Compliance Status, you must submit a file in portable document format (PDF) to CEDRI. The reports must be submitted by the deadlines specified in this subpart, regardless of the method in which the reports are submitted.

(3) If you are required to electronically submit a report through CEDRI in EPA's CDX, you may assert a claim of EPA system outage for failure to timely comply with the reporting requirement. To assert a claim of EPA system outage, you must meet the requirements outlined in paragraphs (d)(3)(i) through (vii) of this section.

(i) You must have been or will be precluded from accessing CEDRI and submitting a required report within the time prescribed due to an outage of either EPA's CEDRI or CDX systems.

(ii) The outage must have occurred within the period of time beginning five business days prior to the date that the submission is due.

(iii) The outage may be planned or unplanned.

(iv) You must submit notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(v) You must provide to the Administrator a written description identifying:

(A) The date(s) and time(s) when CDX or CEDRI was accessed and the system was unavailable;

(B) A rationale for attributing the delay in reporting beyond the regulatory deadline to EPA system outage;

(C) Measures taken or to be taken to minimize the delay in reporting; and

(D) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(vi) The decision to accept the claim of EPA system outage and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(vii) In any circumstance, the report must be submitted electronically as soon as possible after the outage is resolved.

(4) If you are required to electronically submit a report through CEDRI in EPA's CDX, you may assert a claim of force majeure for failure to timely comply with the reporting requirement. To assert a claim of force majeure, you must meet the requirements outlined in paragraphs (d)(4)(i) through (v) of this section.

(i) You may submit a claim if a force majeure event is about to occur, occurs, or has occurred or there are lingering effects from such an event within the period of time beginning five business days prior to the date the submission is due. For the purposes of this section, a force majeure event is defined as an event that will be or has been caused by circumstances beyond the control of the affected facility, its contractors, or any entity controlled by the affected facility that prevents you from complying with the requirement to submit a report electronically within the time period prescribed. Examples of such events are acts of nature (*e.g.,* hurricanes, earthquakes, or floods), acts of war or terrorism, or equipment failure or safety hazard beyond the control of the affected facility (*e.g.,* large scale power outage).

(ii) You must submit the notification to the Administrator in writing as soon as possible following the date you first knew, or through due diligence should have known, that the event may cause or has caused a delay in reporting.

(iii) You must provide to the Administrator:

(A) A written description of the force majeure event;

(B) A rationale for attributing the delay in reporting beyond the regulatory deadline to the force majeure event;

(C) Measures taken or to be taken to minimize the delay in reporting; and

(D) The date by which you propose to report, or if you have already met the reporting requirement at the time of the notification, the date you reported.

(iv) The decision to accept the claim of force majeure and allow an extension to the reporting deadline is solely within the discretion of the Administrator.

(v) In any circumstance, the reporting must occur as soon as possible after the force majeure event occurs.

■ 9. Section 63.4730 is amended by:

■ a. Revising paragraph (c)(3) and paragraph (k) introductory text;

■ b. Redesignating paragraphs (k)(1) through (4) as paragraphs (k)(1)(i) through (iv);

■ c. Adding paragraph (k)(1) introductory text and paragraph (k)(2);

■ d. Redesignating paragraphs (k)(5)(i) through (iii) as paragraphs (k)(1)(v)(A) through (C);

■ e. Redesignating paragraph (k)(5) introductory text as paragraph (k)(1)(v) introductory text and revising it;

■ f. Redesignating paragraphs (k)(6)(i) and (ii) as paragraphs (k)(1)(vi)(A) and (B);

■ g. Redesignating paragraph (k)(6) introductory text as paragraph (k)(1)(vi) introductory text and revising it; and

■ h. Redesignating paragraphs (k)(7) and (8) as paragraphs (k)(1)(vii) and (viii).

The revisions and additions read as follows:

§ 63.4730 What records must I keep?

* * * * *

(c) * * *

(3) For the emission rate without add-on controls option, a record of the calculation of the total mass of organic HAP emissions for the coatings, thinners, and cleaning materials used each month, using Equations 1, 1A (or 1A-alt) through 1C, and 2 of § 63.4751; and, if applicable, the calculation used to determine mass of organic HAP in waste materials according to § 63.4751(e)(4); the calculation of the total volume of coating solids used each month, using Equation 2 of § 63.4751; and the calculation of each 12-month organic HAP emission rate, using Equation 3 of § 63.4751.

* * * * *

(k) If you use the emission rate with add-on controls option, you must keep the records specified in paragraphs (k)(1) through (2) of this section.

(1) For existing sources, before September 3, 2019:

* * * * *

(v) For each capture system that is not a PTE, the data and documentation you used to determine capture efficiency according to the requirements specified in §§ 63.4764 and 63.4765(b) through (e), including the records specified in paragraphs (k)(1)(v)(A) through (C) of this section that apply to you.

* * * * *

(vi) The records specified in paragraphs (k)(1)(vi)(A) and (B) of this section for each add-on control device organic HAP destruction or removal efficiency determination as specified in § 63.4766.

* * * * *

(2) After March 4, 2019 for new and reconstructed sources, and on and after September 3, 2019 for existing sources:

(i) The records required to show continuous compliance with each operating limit specified in Table 3 to this subpart that applies to you.

(ii) For each capture system that is a PTE, the data and documentation you used to support a determination that the capture system meets the criteria in Method 204 of appendix M to 40 CFR part 51 for a PTE and has a capture efficiency of 100 percent, as specified in § 63.4765(a).

(iii) For each capture system that is not a PTE, the data and documentation

you used to determine capture efficiency according to the requirements specified in §§ 63.4764 and 63.4765(b) through (e), including the records specified in paragraphs (k)(2)(iii)(A) through (C) of this section that apply to you.

(A) *Records for a liquid-to-uncaptured-gas protocol using a temporary total enclosure or building enclosure.* Records of the mass of total volatile hydrocarbon (TVH) as measured by Method 204A or F of appendix M to 40 CFR part 51 for each material used in the coating operation, and the total TVH for all materials used during each capture efficiency test run, including a copy of the test report. Records of the mass of TVH emissions not captured by the capture system that exited the temporary total enclosure or building enclosure during each capture efficiency test run as measured by Method 204D or E of appendix M to 40 CFR part 51, including a copy of the test report. Records documenting that the enclosure used for the capture efficiency test met the criteria in Method 204 of appendix M to 40 CFR part 51 for either a temporary total enclosure or a building enclosure.

(B) *Records for a gas-to-gas protocol using a temporary total enclosure or a building enclosure.* Records of the mass of TVH emissions captured by the emission capture system as measured by Method 204B or C of appendix M to 40 CFR part 51 at the inlet to the add-on control device, including a copy of the test report. Records of the mass of TVH emissions not captured by the capture system that exited the temporary total enclosure or building enclosure during each capture efficiency test run as measured by Method 204D or E of appendix M to 40 CFR part 51, including a copy of the test report. Records documenting that the enclosure used for the capture efficiency test met the criteria in Method 204 of appendix M to 40 CFR part 51 for either a temporary total enclosure or a building enclosure.

(C) *Records for an alternative protocol.* Records needed to document a capture efficiency determination using an alternative method or protocol as specified in § 63.4765(e), if applicable.

(iv) The records specified in paragraphs (k)(2)(iv)(A) and (B) of this section for each add-on control device organic HAP destruction or removal efficiency determination as specified in § 63.4766.

(A) Records of each add-on control device performance test conducted according to §§ 63.4764 and 63.4766.

(B) Records of the coating operation conditions during the add-on control device performance test showing that the performance test was conducted under representative operating conditions.

(v) Records of the data and calculations you used to establish the emission capture and add-on control device operating limits as specified in § 63.4767 and to document compliance with the operating limits as specified in Table 3 to this subpart.

(vi) A record of the work practice plan required by § 63.4693, and documentation that you are implementing the plan on a continuous basis.

■ 10. Section 63.4741 is amended by revising:

■ a. Paragraph (a)(2);

■ b. The subject heading and first sentence of paragraph (b)(1);

■ c. The defined terms ''$m_{volatiles}$'' and ''D_{avg}'' in Equation 1 in paragraph (b)(3) introductory text; and

■ d. Paragraph (c).

The revisions read as follows:

§ 63.4741 How do I demonstrate initial compliance with the emission limitations?

* * * * *

(a) * * *

(2) *Method 24 (appendix A–7 to 40 CFR part 60).* For coatings, you may use Method 24 to determine the mass fraction of nonaqueous volatile matter and use that value as a substitute for mass fraction of organic HAP. (**Note:** Method 24 is not appropriate for those coatings with a water content that would result in an effective detection limit greater than the applicable emission limit.) One of the voluntary consensus standards in paragraphs (a)(2)(i) through (iv) may be used as an alternative to using Method 24.

(i) ASTM Method D2111–10 (Reapproved 2015), ''Standard Test Methods for Specific Gravity and Density of Halogenated Organic Solvents and Their Admixtures,'' (incorporated by reference, see § 63.14);

(ii) ASTM Method D2369–10 (Reapproved 2015)[e], ''Standard Test Method for Volatile Content of Coatings,'' (incorporated by reference, see § 63.14);

(iii) ASTM Method D2697–03 (Reapproved 2014), ''Standard Test Method for Volume Nonvolatile Matter in Clear or Pigmented Coatings,'' (incorporated by reference, see § 63.14); and

(iv) ASTM Method D6093–97 (Reapproved 2016), ''Standard Test Method for Percent Volume Nonvolatile Matter in Clear or Pigmented Coatings Using a Helium Gas Pycnometer,'' (incorporated by reference, see § 63.14).

* * * * *

(b) * * *

(1) *ASTM Method D2697–03 (Reapproved 2014) or D6093–97 (Reapproved 2016).* You may use ASTM Method D2697–03 (Reapproved 2014), ''Standard Test Method for Volume Nonvolatile Matter in Clear or Pigmented Coatings'' (incorporated by reference, see § 63.14), or D6093–97 (Reapproved 2016), ''Standard Test Method for Percent Volume Nonvolatile Matter in Clear or Pigmented Coatings Using a Helium Gas Pycnometer'' (incorporated by reference, see § 63.14), to determine the volume fraction of coating solids for each coating. * * *

* * * * *

(3) * * *

$m_{volatiles}$ = Total volatile matter content of the coating, including HAP, volatile organic compounds (VOC), water, and exempt compounds, determined according to Method 24 in appendix A–7 of 40 CFR part 60, grams volatile matter per liter coating.

D_{avg} = Average density of volatile matter in the coating, grams volatile matter per liter volatile matter, determined from test results using ASTM Method D1475–13, ''Standard Test Method for Density of Liquid Coatings, Inks, and Related Products,'' (incorporated by reference, see § 63.14), information from the supplier or manufacturer of the material, or reference sources providing density or specific gravity data for pure materials. If there is disagreement between ASTM Method D1475–13 test results and other information sources, the test results will take precedence.

(c) *Determine the density of each coating.* Determine the density of each coating used during the compliance period from test results using ASTM Method D1475–13, ''Standard Test Method for Density of Liquid Coatings, Inks, and Related Products,'' (incorporated by reference, see § 63.14), or information from the supplier or manufacturer of the material. If there is disagreement between ASTM Method D1475–13 test results and the supplier's or manufacturer's information, the test results will take precedence.

* * * * *

■ 11. Section 63.4751 is amended by:

■ a. Revising paragraph (c);

■ b. Revising the defined term ''A'' in Equation 1 in of paragraph (e) introductory text; and

■ c. Adding paragraph (i).

The revisions and addition read as follows:

§ 63.4751 How do I demonstrate initial compliance with the emission limitations?

* * * * *

(c) *Determine the density of each material.* Determine the density of each coating, thinner, and cleaning material

used during each month from test results using ASTM Method D1475–13 (incorporated by reference, see § 63.14), information from the supplier or manufacturer of the material, or reference sources providing density or specific gravity data for pure materials. If there is disagreement between ASTM Method D1475–13 test results and such other information sources, the test results will take precedence.

* * * * *

(e) * * *

A = Total mass of organic HAP in the coatings used during the month, grams, as calculated in Equation 1A (or 1A-alt) of this section.

* * * * *

(i) *Alternative compliance demonstration.* As an alternative to paragraph (h) of this section, you may demonstrate initial compliance by identifying each organic HAP component in the coating(s) and conducting a performance test using Method 320 of appendix A to 40 CFR part 63 or NCASI Method ISS/FP A105.01 (incorporated by reference in § 63.14) (for formaldehyde) or Method 326 of appendix A to 40 CFR part 63 (for isocyanates) to obtain an organic HAP emission factor (EF). The voluntary consensus standard ASTM D6348–03 (Reapproved 2010) (incorporated by reference, see § 63.14) may be used as an alternative to using Method 320 under the conditions specified in paragraphs (i)(4)(i) and (ii) of this section.

(1) You must also calculate the mass of organic HAP emitted from the coatings used during the month using Equation 1A-alt of this section:

$$A = \sum_{i=1}^{m} (Vol_{c,i})(D_{c,i})(W_{c,i})(EF_{c,i}) \qquad (Eq. 1A - alt)$$

Where:

A = Total mass of organic HAP in the coatings used during the month, grams.

$Vol_{c,i}$ = Total volume of coating, i, used during the month, liters.

$D_{c,j}$ = Density of coating, i, grams coating per liter of coatings.

$W_{c,i}$ = Mass fraction of organic HAP in coating, i, grams organic HAP per gram coating.

$EF_{c,i}$ = Organic HAP emission factor (three-run average from performance testing, evaluated as proportion of mass organic HAP emitted to mass of organic HAP in the coatings used during the performance test).

m = Number of different coatings used during the month.

(2) Calculate the organic HAP emission rate for the 12-month compliance period, grams organic HAP per liter coating solids used, using Equation 3 of this section.

(3) The organic HAP emission rate for the initial 12-month compliance period, calculated using Equation 3 of this section, must be less than or equal to the applicable emission limit in § 63.4690. You must keep all records as required by §§ 63.4730 and 63.4731. As part of the Notification of Compliance Status required by § 63.4710, you must identify the coating operation(s) for which you used the emission rate without add-on controls option and submit a statement that the coating operation(s) was (were) in compliance with the emission limitations during the initial compliance period because the organic HAP emission rate was less than or equal to the applicable emission limit in § 63.4690, determined according to this section.

(4) If ASTM D6348–03 (Reapproved 2010) is used, the conditions specified in paragraphs (i)(4)(i) and (ii) must be met.

(i) Test plan preparation and implementation in the Annexes to ASTM D6348–03 (Reapproved 2010), sections A1 through A8 are mandatory.

(ii) In ASTM D6348–03 (Reapproved 2010) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5 of ASTM D6348–03). In order for the test data to be acceptable for a compound, %R must be between 70 and 130 percent. If the %R value does not meet this criterion for a target compound, the test data are not acceptable for that compound, and the test must be repeated for that analyte following adjustment of the sampling and/or analytical procedure before the retest. The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound using the following equation: Reported Result = (Measured Concentration in the Stack × 100)/%R.

■ 12. Section 63.4752 is amended by adding paragraph (e) to read as follows:

§ 63.4752 How do I demonstrate continuous compliance with the emission limitations?

* * * * *

(e) If you use the alternative compliance demonstration described in § 63.4751(i), you must identify each organic HAP component in the coating(s) and conduct a performance test every 5 years to obtain an organic HAP emission factor (EF). You must use the following methods, as appropriate: Method 320 of appendix A to 40 CFR part 63 or NCASI Method ISS/FP A105.01 (incorporated by reference, see § 63.14) (for formaldehyde) or Method 326 of appendix A to 40 CFR part 63 (for isocyanates). The voluntary consensus standard ASTM D6348–03 (Reapproved 2010) (incorporated by reference, see § 63.14) may be used as an alternative to using Method 320 under the conditions specified in § 63.4751(i)(4)(i) and (ii).

■ 13. Section 63.4761 is amended by revising paragraph (j)(3) to read as follows:

§ 63.4761 How do I demonstrate initial compliance?

* * * * *

(j) * * *

(3) Determine the mass fraction of volatile organic matter for each coating, thinner, and cleaning material used in the coating operation controlled by the solvent recovery system during the month, grams volatile organic matter per gram coating. You may determine the volatile organic matter mass fraction using Method 24 of 40 CFR part 60, appendix A–7, one of the voluntary consensus standards specified in § 63.4741(a)(2)(i) through (iv), or an EPA approved alternative method, or you may use information provided by the manufacturer or supplier of the coating. In the event of any inconsistency between information provided by the manufacturer or supplier and the results of Method 24 of 40 CFR part 60, appendix A–7, or an approved alternative method, the test method results will take precedence unless after consultation, a regulated source could demonstrate to the satisfaction of the enforcement agency that the formulation data were correct.

* * * * *

■ 14. Section 63.4763 is amended by revising paragraph (h) to read as follows:

§ 63.4763 How do I demonstrate continuous compliance with the emission limitations?

* * * * *

(h) For existing sources, before September 3, 2019, consistent with §§ 63.6(e) and 63.7(e)(1), deviations that occur during a period of SSM of the

emission capture system, add-on control device, or coating operation that may affect emission capture or control device efficiency are not violations if you demonstrate to the Administrator's satisfaction that you were operating in accordance with § 63.6(e)(1). The Administrator will determine whether deviations that occur during a period you identify as an SSM are violations, according to the provisions in § 63.6(e).

* * * * *

■ 15. Section 63.4764 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 63.4764 What are the general requirements for performance tests?

(a) * * *

(1) *Representative coating operation operating conditions.* You must conduct the performance test under representative operating conditions for the coating operation. Operations during periods of startup, shutdown, and nonoperation do not constitute representative conditions. You may not conduct performance tests during periods of malfunction. You must record the process information that is necessary to document operating conditions during the test and explain why the conditions represent normal operation. Upon request, you shall make available to the Administrator such records as may be necessary to determine the conditions of performance tests.

(2) *Representative emission capture system and add-on control device operating conditions.* You must conduct the performance test when the emission capture system and add-on control device are operating at a representative flow rate, and the add-on control device is operating at a representative inlet concentration. Representative conditions exclude periods of startup and shutdown. You may not conduct performance tests during periods of malfunction. You must record information that is necessary to document emission capture system and add-on control device operating conditions during the test and explain why the conditions represent normal operation.

* * * * *

■ 16. Section 63.4766 is amended by revising paragraphs (a)(1) through (4), (b), (d), and (f) to read as follows:

§ 63.4766 How do I determine the add-on control device emission destruction or removal efficiency?

* * * * *

(a) * * *

(1) Use Method 1 or 1A of appendix A–1 to 40 CFR part 60, as appropriate, to select sampling sites and velocity traverse points.

(2) Use Method 2, 2A, 2C, 2D, or 2F of appendix A–1 to 40 CFR part 60, or Method 2G of appendix A–2 to 40 CFR part 60, as appropriate, to measure gas volumetric flow rate.

(3) Use Method 3, 3A, or 3B of appendix A–2 to 40 CFR part 60, as appropriate, for gas analysis to determine dry molecular weight. You may also use as an alternative to Method 3B, the manual method for measuring the oxygen, carbon dioxide, and carbon monoxide content of exhaust gas in ANSI/ASME PTC 19.10–1981, ''Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus]'' (incorporated by reference, see § 63.14).

(4) Use Method 4 of appendix A–3 to 40 CFR part 60 to determine stack gas moisture.

* * * * *

(b) Measure total gaseous organic mass emissions as carbon at the inlet and outlet of the add-on control device simultaneously, using Method 25 or 25A of appendix A–7 to 40 CFR part 60, and Method 320 or 326 of appendix A to 40 CFR part 63, as specified in paragraphs (b)(1) through (5) of this section. The voluntary consensus standard ASTM D6348–03 (Reapproved 2010) (incorporated by reference in § 63.14) may be used as an alternative to using Method 320 if the conditions specified in § 63.4751(i)(4)(i) and (ii) are met. You must use the same method for both the inlet and outlet measurements.

(1) Use Method 25 of appendix A–7 to 40 CFR part 60 if the add-on control device is an oxidizer, and you expect the total gaseous organic concentration as carbon to be more than 50 parts per million (ppm) at the control device outlet.

(2) Use Method 25A of appendix A–7 to 40 CFR part 60 if the add-on control device is an oxidizer, and you expect the total gaseous organic concentration as carbon to be 50 ppm or less at the control device outlet.

(3) Use Method 25A of appendix A–7 to 40 CFR part 60 if the add-on control device is not an oxidizer.

(4) If Method 25A is used, and if formaldehyde is a major organic HAP component of the surface coating exhaust stream, use Method 320 of appendix A to 40 CFR part 63 or NCASI Method ISS/FP A105.01 (incorporated by reference in § 63.14) or ASTM D6348–03 (Reapproved 2010) (incorporated by reference in § 63.14) to determine formaldehyde concentration.

(5) In addition to Method 25 or 25A, use Method 326 of appendix A to 40 CFR part 63 if isocyanate is a major organic HAP component of the surface coating exhaust stream.

* * * * *

(d) For each test run, determine the total gaseous organic emissions mass flow rates for the inlet and the outlet of the add-on control device, using Equation 1 of this section. If there is more than one inlet or outlet to the add-on control device, you must calculate the total gaseous organic mass flow rate using Equation 1 of this section for each inlet and each outlet and then total all of the inlet emissions and total all of the outlet emissions. The mass emission rates for formaldehyde and individual isocyanate must be determined separately.

$$M_f = Q_{sd} C_c MW (41.6)(10^{-6}) \qquad (Eq. 1)$$

Where:

M_f = Total gaseous organic emissions mass flow rate, grams per hour (h).

MW = Molecular weight of analyte of interest (12 for Method 25 and 25A results).

C_c = Concentration of organic compounds in the vent gas (as carbon if determined by Method 25 or Method 25A), parts per million by volume (ppmv), dry basis.

Q_{sd} = Volumetric flow rate of gases entering or exiting the add-on control device, as determined by Method 2, 2A, 2C, 2D, 2F, or 2G, dry standard cubic meters/hour (dscm/h).

41.6 = Conversion factor for molar volume, gram-moles per cubic meter (mol/m^3) (@ 293 Kelvin (K) and 760 millimeters of mercury (mmHg)).

* * * * *

(f) Determine the emission destruction or removal efficiency of the add-on control device as the average of the efficiencies determined in the three test runs and calculated in Equation 2 of this section. Destruction and removal efficiency must be determined independently for formaldehyde and isocyanates.

■ 17. Section 63.4781 is amended by revising paragraph (3) under the definition of ''deviation'' and revising the definition of ''tileboard'' to read as follows:

§ 63.4781 What definitions apply to this subpart?

* * * * *

Deviation * * *

(3) On and after September 3, 2019, fails to meet any emission limit, or operating limit, or work practice standard in this subpart during SSM.

* * * * *

Tileboard means hardboard that meets the specifications for Class I given by the standard ANSI A135.4–2012 (incorporated by reference, see § 63.14) as approved by the American National Standards Institute. The standard specifies requirements and test methods for water absorption, thickness swelling, modulus of rupture, tensile strength, surface finish, dimensions, squareness, edge straightness, and moisture content for five classes of hardboard. Tileboard is also known as Class I hardboard or tempered hardboard.

* * * * *

■ 18. Table 4 to Subpart QQQQ is revised to read as follows:

Table 4 to Subpart QQQQ of Part 63—Applicability of General Provisions to Subpart QQQQ of Part 63

You must comply with the applicable General Provisions requirements according to the following table:

Citation	Subject	Applicable to subpart QQQQ	Explanation
§ 63.1(a)(1)–(14)	General Applicability	Yes.	
§ 63.1(b)(1)–(3)	Initial Applicability Determination	Yes	Applicability to subpart QQQQ is also specified in § 63.4681.
§ 63.1(c)(1)	Applicability After Standard Established	Yes.	
§ 63.1(c)(2)	Applicability of Permit Program for Area Sources	No	Area sources are not subject to subpart QQQQ.
§ 63.1(c)(3)	[Reserved]	No.	
§ 63.1(c)(4)–(5)	Extensions and Notifications	Yes.	
§ 63.1(d)	[Reserved]	No.	
§ 63.1(e)	Applicability of Permit Program Before Relevant Standard is Set.	Yes.	
§ 63.2	Definitions	Yes	Additional definitions are specified in § 63.4781.
§ 63.3(a)–(c)	Units and Abbreviations	Yes.	
§ 63.4(a)(1)–(5)	Prohibited Activities	Yes.	
§ 63.4(b)–(c)	Circumvention/Severability	Yes.	
§ 63.5(a)	Construction/Reconstruction	Yes.	
§ 63.5(b)(1)–(6)	Requirements for Existing, Newly Constructed, and Reconstructed Sources.	Yes.	
§ 63.5(c)	[Reserved]	No.	
§ 63.5(d)	Application for Approval of Construction/Reconstruction.	Yes.	
§ 63.5(e)	Approval of Construction/Reconstruction	Yes.	
§ 63.5(f)	Approval of Construction/Reconstruction Based on Prior State Review.	Yes.	
§ 63.6(a)	Compliance With Standards and Maintenance Requirements—Applicability.	Yes.	
§ 63.6(b)(1)–(7)	Compliance Dates for New and Reconstructed Sources.	Yes	§ 63.4683 specifies compliance dates.
§ 63.6(c)(1)–(5)	Compliance Dates for Existing Sources	Yes	§ 63.4683 specifies compliance dates.
§ 63.6(d)	[Reserved]	No.	
§ 63.6(e)(1)(i)	General Duty to Minimize Emissions	No	See § 63.4700(b) for general duty requirement.
§ 63.6(e)(1)(ii)	Requirement to Correct Malfunctions ASAP	No.	
§ 63.6(e)(1)(iii)	Operation and Maintenance Requirements Enforceable Independent of Emissions Limitations.	Yes.	
§ 63.6(e)(2)	[Reserved]	No.	
§ 63.6(e)(3)	SSMP	No.	
§ 63.6(f)(1)	Compliance Except During SSM	No.	
§ 63.6(f)(2)–(3)	Methods for Determining Compliance	Yes.	
§ 63.6(g)(1)–(3)	Use of an Alternative Standard	Yes.	
§ 63.6(h)	Compliance with Opacity/Visible Emissions Standards.	No	Subpart QQQQ does not establish opacity standards and does not require continuous opacity monitoring systems (COMS).
§ 63.6(i)(1)–(16)	Extension of Compliance	Yes.	
§ 63.6(j)	Presidential Compliance Exemption	Yes.	
§ 63.7(a)(1)	Performance Test Requirements—Applicability	Yes	Applies to all affected sources. Additional requirements for performance testing are specified in §§ 63.4751, 63.4752, 63.4764, 63.4765, and 63.4766.
§ 63.7(a)(2)	Performance Test Requirements—Dates	Yes	Applies only to performance tests for capture system and control device efficiency at sources using these to comply with the standard. § 63.4760 specifies the schedule for performance test requirements that are earlier than those specified in § 63.7(a)(2).
§ 63.7(a)(3)	Performance Tests Required By the Administrator.	Yes.	
§ 63.7(a)(4)	Notification of Delay in Performance Testing Due to Force Majeure.	Yes.	

Citation	Subject	Applicable to subpart QQQQ	Explanation
§ 63.7(b)–(d)	Performance Test Requirements—Notification, Quality Assurance, Facilities Necessary for Safe Testing, Conditions During Test.	Yes	Applies only to performance tests for capture system and add-on control device efficiency at sources using these to comply with the standard.
§ 63.7(e)(1)	Performance Testing	Yes.	
§ 63.7(f)	Performance Test Requirements—Use of Alternative Test Method.	Yes	Applies to all test methods except those used to determine capture system efficiency.
§ 63.7(g)–(h)	Performance Test Requirements—Data Analysis, Recordkeeping, Reporting, Waiver of Test.	Yes	Applies only to performance tests for capture system and add-on control device efficiency at sources using these to comply with the standard.
§ 63.8(a)(1)–(2)	Monitoring Requirements—Applicability	Yes	Applies only to monitoring of capture system and add-on control device efficiency at sources using these to comply with the standard. Additional requirements for monitoring are specified in § 63.4768.
§ 63.8(a)(3)	[Reserved]	No.	
§ 63.8(a)(4)	Additional Monitoring Requirements	No	Subpart QQQQ does not have monitoring requirements for flares.
§ 63.8(b)	Conduct of Monitoring	Yes.	
§ 63.8(c)(1)	Continuous Monitoring System (CMS) Operation and Maintenance.	Yes	Applies only to monitoring of capture system and add-on control device efficiency at sources using these to comply with the standard. Additional requirements for CMS operations and maintenance are specified in § 63.4768.
§ 63.8(c)(1)(i)	General Duty to Minimize Emissions and CMS Operation.	No.	
§ 63.8(c)(1)(ii)	Operation and Maintenance of CMS	Yes.	
§ 63.8(c)(1)(iii)	Requirement to Develop SSM Plan for CMS	No.	
§ 63.8(c)(2)–(3)	Monitoring System Installation	Yes.	
§ 63.8(c)(4)	CMSs	No	§ 63.4768 specifies the requirements for the operation of CMS for capture systems and add-on control devices at sources using these to comply.
§ 63.8(c)(5)	COMS	No	Subpart QQQQ does not have opacity for visible emission standards.
§ 63.8(c)(6)	CMS Requirements	Yes	§ 63.4768 specifies the requirements for monitoring systems for capture systems and add-on control devices at sources using these to comply.
§ 63.8(c)(7)	CMS Out-of-Control Periods	Yes.	
§ 63.8(c)(8)	CMS Out-of-Control Periods Reporting	No	§ 63.4720 requires reporting of CMS out-of-control periods.
§ 63.8(d)–(e)	Quality Control Program and CMS Performance Evaluation.	No	Subpart QQQQ does not require the use of continuous emissions monitoring systems.
§ 63.8(f)(1)–(5)	Use of an Alternative Monitoring Method	Yes.	
§ 63.8(f)(6)	Alternative to Relative Accuracy Test	No	Subpart QQQQ does not require the use of continuous emissions monitoring systems.
§ 63.8(g)(1)–(5)	Data Reduction	No	§§ 63.4767 and 63.4768 specify monitoring data reduction.
§ 63.9(a)–(d)	Notification Requirements	Yes.	
§ 63.9(e)	Notification of Performance Test	Yes	Applies only to capture system and add-on control device performance tests at sources using these to comply with the standard.
§ 63.9(f)	Notification of Visible Emissions/Opacity Test	No	Subpart QQQQ does not have opacity or visible emission standards.
§ 63.9(g)(1)–(3)	Additional Notifications When Using CMS	No	Subpart QQQQ does not require the use of continuous emissions monitoring systems.
§ 63.9(h)	Notification of Compliance Status	Yes	§ 63.4710 specifies the dates for submitting the Notification of Compliance Status.
§ 63.9(i)	Adjustment of Submittal Deadlines	Yes.	
§ 63.9(j)	Change in Previous Information	Yes.	
§ 63.10(a)	Recordkeeping/Reporting—Applicability and General Information.	Yes.	
§ 63.10(b)(1)	General Recordkeeping Requirements	Yes	Additional requirements are specified in §§ 63.4730 and 63.4731.
§ 63.10(b)(2)(i)–(ii)	Recordkeeping of Occurrence and Duration of Startups and Shutdowns.	No.	
§ 63.10(b)(2)(iii)	Recordkeeping Relevant to CMS	Yes.	
§ 63.10(b)(2)(iv)–(v)	Recordkeeping Relevant to SSM	No.	
§ 63.10(b)(2)(vi)–(xi)	Recordkeeping for CMS Malfunctions	Yes.	
§ 63.10(b)(2)(xii)	Records	Yes.	

Citation	Subject	Applicable to subpart QQQQ	Explanation
§ 63.10(b)(2)(xiii)		No	Subpart QQQQ does not require the use of continuous emissions monitoring systems.
§ 63.10(b)(2)(xiv)		Yes.	
§ 63.10(b)(3)	Recordkeeping Requirements for Applicability Determinations.	Yes.	
§ 63.10(c)(1)–(6)	Additional Recordkeeping Requirements for Sources with CMS.	Yes.	
§ 63.10(c)(7)–(8)		No	The same records are required in § 63.4720(a)(7).
§ 63.10(c)(9)–(14)		Yes.	
§ 63.10(c)(15)	Use of SSM Plan	No.	
§ 63.10(d)(1)	General Reporting Requirements	Yes	Additional requirements are specified in § 63.4720.
§ 63.10(d)(2)	Report of Performance Test Results	Yes	Additional requirements are specified in § 63.4720(b).
§ 63.10(d)(3)	Reporting Opacity or Visible Emissions Observations.	No	Subpart QQQQ does not require opacity or visible emissions observations.
§ 63.10(d)(4)	Progress Reports for Sources With Compliance Extensions.	Yes.	
§ 63.10(d)(5)	SSM Reports	No	Malfunctions shall be reported based on compliance option under § 63.4720(a)(5–7).
§ 63.10(e)(1)–(2)	Additional CMS Reports	No	Subpart QQQQ does not require the use of continuous emissions monitoring systems.
§ 63.10(e)(3)	Excess Emissions/CMS Performance Reports	No	§ 63.4720(b) specifies the contents of periodic compliance reports.
§ 63.10(e)(4)	COMS Data Reports	No	Subpart QQQQ does not specify requirements for opacity or COMS.
§ 63.10(f)	Recordkeeping/Reporting Waiver	Yes.	
§ 63.11	Control Device Requirements/Flares	No	Subpart QQQQ does not specify use of flares for compliance.
§ 63.12	State Authority and Delegations	Yes.	
§ 63.13	Addresses	Yes.	
§ 63.14	Incorporation by Reference	Yes	Test Methods ANSI A135.4–2012, ANSI/ASME PTC 19.10–1981, Part 10, ASTM D1475–13, ASTM D2111–10 (Reapproved 2015), ASTM D2369–10 (Reapproved 2015)[e], ASTM D2697–03 (Reapproved 2014), ASTM D4840–99 (2018)[e], ASTM D6093–97 (Reapproved 2016), ASTM D6348–03 (Reapproved 2010) and NCASI Method ISS/FP A105.01 (incorporated by reference, see § 63.14).
§ 63.15	Availability of Information/Confidentiality	Yes.	
§ 63.16	Requirements for Performance Track Member Facilities.	Yes.	

■ 19. Appendix A to part 63 is amended by adding Method 326 in numerical order to read as follows:

Appendix A to Part 63—Test Methods

* * * * *

Method 326—Method for Determination of Isocyanates in Stationary Source Emissions

1.0 Scope and Application

This method is applicable to the collection and analysis of isocyanate compounds from the emissions associated with manufacturing processes. This method is not inclusive with respect to specifications (*e.g.,* equipment and supplies) and sampling procedures essential to its performance. Some material is incorporated by reference from other EPA methods. Therefore, to obtain reliable results, persons using this method should have a thorough knowledge of at least Method 1, Method 2, Method 3, and Method 5 found in Appendices A–1, A–2, and A–3 in Part 60 of this title.

1.1 Analytes. This method is designed to determine the mass emission of isocyanates being emitted from manufacturing processes. The following is a table (Table 1–1) of the isocyanates and the manufacturing process at which the method has been evaluated:

TABLE 326–1—ANALYTES

Compound's name	CAS No.	Detection limit (ng/m^3)[a]	Manufacturing process
2,4-Toluene Diisocyanate (TDI)	584–84–9	106	Flexible Foam Production.
1,6-Hexamethylene Diisocyanate (HDI)	822–06–0	396	Paint Spray Booth.
Methylene Diphenyl Diisocyanate (MDI)	101–68–8	112	Pressed Board Production.
Methyl Isocyanate (MI)	624–83–0	228	Not used in production.

[a] Estimated detection limits are based on a sample volume of 1 m^3 and a 10-ml sample extraction volume.

1.2 Applicability. Method 326 is a method designed for determining compliance with National Emission Standards for Hazardous Air Pollutants (NESHAP). Method 326 may also be specified by New Source Performance Standards (NSPS), State Implementation Plans (SIPs), and operating permits that require measurement of isocyanates in stationary source emissions, to determine compliance with an applicable emission standard or limit.

1.3 Data Quality Objectives (DQO). The principal objective is to ensure the accuracy of the data at the actual emissions levels and in the actual emissions matrix encountered. To meet this objective, method performance tests are required and NIST-traceable calibration standards must be used.

2.0 Summary of Method

2.1 Gaseous and/or aerosol isocyanates are withdrawn from an emission source at an isokinetic sampling rate and are collected in a multicomponent sampling train. The primary components of the train include a heated probe, three impingers containing derivatizing reagent in toluene, an empty impinger, an impinger containing charcoal, and an impinger containing silica gel.

2.2 The liquid impinger contents are recovered, concentrated to dryness under vacuum, brought to volume with acetonitrile (ACN) and analyzed with a high pressure liquid chromatograph (HPLC).

3.0 Definitions [Reserved]

4.0 Interferences

4.1 The greatest potential for interference comes from an impurity in the derivatizing reagent, 1-(2-pyridyl)piperazine (1,2-PP). This compound may interfere with the resolution of MI from the peak attributed to unreacted 1,2-PP.

4.2 Other interferences that could result in positive or negative bias are (1) alcohols that could compete with the 1,2-PP for reaction with an isocyanate and (2) other compounds that may co-elute with one or more of the derivatized isocyanates.

4.3 Method interferences may be caused by contaminants in solvents, reagents, glassware, and other sample processing hardware. All these materials must be routinely shown to be free from interferences under conditions of the analysis by preparing and analyzing laboratory method (or reagent) blanks.

4.3.1 Glassware must be cleaned thoroughly before using. The glassware should be washed with laboratory detergent in hot water followed by rinsing with tap water and distilled water. The glassware may be dried by baking in a glassware oven at 400 °C for at least one hour. After the glassware has cooled, it should be rinsed three times with methylene chloride and three times with acetonitrile. Volumetric glassware should not be heated to 400 °C. Instead, after washing and rinsing, volumetric glassware may be rinsed with acetonitrile followed by methylene chloride and allowed to dry in air.

4.3.2 The use of high purity reagents and solvents helps to reduce interference problems in sample analysis.

5.0 Safety

5.1 Organizations performing this method are responsible for maintaining a current awareness file of Occupational Safety and Health Administration (OSHA) regulations regarding safe handling of the chemicals specified in this method. A reference file of material safety data sheets should also be made available to all personnel involved in performing the method. Additional references to laboratory safety are available.

6.0 Equipment and Supplies

6.1 Sample Collection. A schematic of the sampling train used in this method is shown in Figure 207–1. This sampling train configuration is adapted from Method 5 procedures, and, as such, most of the required equipment is identical to that used in Method 5 determinations. The only new component required is a condenser.

6.1.1 Probe Nozzle. Borosilicate or quartz glass; constructed and calibrated according to Method 5, sections 6.1.1.1 and 10.1, and coupled to the probe liner using a Teflon union; a stainless steel nut is recommended for this union. When the stack temperature exceeds 210 °C (410 °F), a one-piece glass nozzle/liner assembly must be used.

6.1.2 Probe Liner. Same as Method 5, section 6.1.1.2, except metal liners shall not be used. Water-cooling of the stainless steel sheath is recommended at temperatures exceeding 500 °C (932 °F). Teflon may be used in limited applications where the minimum stack temperature exceeds 120 °C (250 °F) but never exceeds the temperature where Teflon is estimated to become unstable [approximately 210 °C (410 °F)].

6.1.3 Pitot Tube, Differential Pressure Gauge, Filter Heating System, Metering System, Barometer, Gas Density Determination Equipment. Same as Method 5, sections 6.1.1.3, 6.1.1.4, 6.1.1.6, 6.1.1.9, 6.1.2, and 6.1.3.

6.1.4 Impinger Train. Glass impingers are connected in series with leak-free ground-glass joints following immediately after the heated probe. The first impinger shall be of the Greenburg-Smith design with the standard tip. The remaining five impingers shall be of the modified Greenburg-Smith design, modified by replacing the tip with a 1.3-cm (½-in.) I.D. glass tube extending about 1.3 cm (½ in.) from the bottom of the outer cylinder. A water-jacketed condenser is placed between the outlet of the first impinger and the inlet to the second impinger to reduce the evaporation of toluene from the first impinger.

6.1.5 Moisture Measurement. For the purpose of calculating volumetric flow rate and isokinetic sampling, you must also collect either Method 4 in Appendix A–3 to this part or other moisture measurement methods approved by the Administrator concurrent with each Method 326 test run.

6.2 Sample Recovery

6.2.1 Probe and Nozzle Brushes; Polytetrafluoroethylene (PTFE) bristle brushes with stainless steel wire or PTFE handles are required. The probe brush shall have extensions constructed of stainless steel, PTFE, or inert material at least as long as the probe. The brushes shall be properly sized and shaped to brush out the probe liner and the probe nozzle.

6.2.2 Wash Bottles. Three. PTFE or glass wash bottles are recommended; polyethylene wash bottles must not be used because organic contaminants may be extracted by exposure to organic solvents used for sample recovery.

6.2.3 Glass Sample Storage Containers. Chemically resistant, borosilicate amber glass bottles, 500-mL or 1,000-mL. Bottles should be tinted to prevent the action of light on the sample. Screw-cap liners shall be either PTFE or constructed to be leak-free and resistant to chemical attack by organic recovery solvents. Narrow-mouth glass bottles have been found to leak less frequently.

6.2.4 Graduated Cylinder. To measure impinger contents to the nearest 1 ml or 1 g. Graduated cylinders shall have subdivisions not >2 mL.

6.2.5 Plastic Storage Containers. Screw-cap polypropylene or polyethylene containers to store silica gel and charcoal.

6.2.6 Funnel and Rubber Policeman. To aid in transfer of silica gel or charcoal to container (not necessary if silica gel is weighed in field).

6.2.7 Funnels. Glass, to aid in sample recovery.

6.3 Sample Preparation and Analysis.

The following items are required for sample analysis.

6.3.1 Rotary Evaporator. Buchii Model EL–130 or equivalent.

6.3.2 1000 ml Round Bottom Flask for use with a rotary evaporator.

6.3.3 Separatory Funnel. 500-ml or larger, with PTFE stopcock.

6.3.4 Glass Funnel. Short-stemmed or equivalent.

6.3.5 Vials. 15-ml capacity with PTFE lined caps.

6.3.6 Class A Volumetric Flasks. 10-ml for bringing samples to volume after concentration.

6.3.7 Filter Paper. Qualitative grade or equivalent.

6.3.8 Buchner Funnel. Porcelain with 100 mm ID or equivalent.

6.3.9 Erlenmeyer Flask. 500-ml with side arm and vacuum source.

6.3.10 HPLC with at least a binary pumping system capable of a programmed gradient.

6.3.11 Column Systems Column systems used to measure isocyanates must be capable of achieving separation of the target compounds from the nearest eluting compound or interferents with no more than 10 percent peak overlap.

6.3.12 Detector. UV detector at 254 nm. A fluorescence detector (FD) with an excitation of 240 nm and an emission at 370 nm may be also used to allow the detection of low concentrations of isocyanates in samples.

6.3.13 Data system for measuring peak areas and retention times.

7.0 Reagents and Standards

7.1 Sample Collection Reagents.

7.1.1 Charcoal. Activated, 6–16 mesh. Used to absorb toluene vapors and prevent them from entering the metering device. Use once with each train and discard.

7.1.2 Silica Gel and Crushed Ice. Same as Method 5, sections 7.1.2 and 7.1.4 respectively

7.1.3 Impinger Solution. The impinger solution is prepared by mixing a known amount of 1-(2-pyridyl) piperazine (purity 99.5+%) in toluene (HPLC grade or equivalent). The actual concentration of 1,2-PP should be approximately four times the amount needed to ensure that the capacity of the derivatizing solution is not exceeded. This amount shall be calculated from the stoichiometric relationship between 1,2-PP and the isocyanate of interest and preliminary information about the concentration of the isocyanate in the stack emissions. A concentration of 130 µg/ml of 1,2-PP in toluene can be used as a reference point. This solution shall be prepared, stored in a refrigerated area away from light, and used within ten days of preparation.

7.2 Sample Recovery Reagents.

7.2.1 Toluene. HPLC grade is required for sample recovery and cleanup (see **Note** to 7.2.2 below).

7.2.2 Acetonitrile. HPLC grade is required for sample recovery and cleanup. **Note:** Organic solvents stored in metal containers may have a high residue blank and should not be used. Sometimes suppliers transfer solvents from metal to glass bottles; thus blanks shall be run before field use and only solvents with a low blank value should be used.

7.3 Analysis Reagents. Reagent grade chemicals should be used in all tests. All reagents shall conform to the specifications of the Committee on Analytical Reagents of the American Chemical Society, where such specifications are available.

7.3.1 Toluene, $C_6H_5CH_3$. HPLC Grade or equivalent.

7.3.2 Acetonitrile, CH_3CN (ACN). HPLC Grade or equivalent.

7.3.3 Methylene Chloride, CH_2Cl_2. HPLC Grade or equivalent.

7.3.4 Hexane, C_6H_{14}. HPLC Grade or equivalent.

7.3.5 Water, H_2O. HPLC Grade or equivalent.

7.3.6 Ammonium Acetate, $CH_3CO_2NH_4$.

7.3.7 Acetic Acid (glacial), CH_3CO_2H.

7.3.8 1-(2-Pyridyl)piperazine, (1,2-PP), ≥99.5% or equivalent.

7.3.9 Absorption Solution. Prepare a solution of 1-(2-pyridyl)piperazine in toluene at a concentration of 40 mg/300 ml. This solution is used for method blanks and method spikes.

7.3.10 Ammonium Acetate Buffer Solution (AAB). Prepare a solution of ammonium acetate in water at a concentration of 0.1 M by transferring 7.705 g of ammonium acetate to a 1,000 ml volumetric flask and diluting to volume with HPLC Grade water. Adjust pH to 6.2 with glacial acetic acid.

8.0 Sample Collection, Storage and Transport

Note: Because of the complexity of this method, field personnel should be trained in and experienced with the test procedures in order to obtain reliable results.

8.1 Sampling

8.1.1 Preliminary Field Determinations. Same as Method 5, section 8.2.

8.1.2 Preparation of Sampling Train. Follow the general procedure given in Method 5, section 8.3.1, except for the following variations: Place 300 ml of the impinger absorbing solution in the first impinger and 200 ml each in the second and third impingers. The fourth impinger shall remain empty. The fifth and sixth impingers shall have 400 g of charcoal and 200–300 g of silica gel, respectively. Alternatively, the charcoal and silica gel may be combined in the fifth impinger. Set-up the train as in Figure 326–1. During assembly, do not use any silicone grease on ground-glass joints.

Note: During preparation and assembly of the sampling train, keep all openings where contamination can occur covered with PTFE film or aluminum foil until just before assembly or until sampling is about to begin.

8.1.3 Leak-Check Procedures. Follow the leak-check procedures given in Method 5, sections 8.4.2 (Pretest Leak-Check), 8.4.3 (Leak-Checks During the Sample Run), and 8.4.4 (Post-Test Leak-Check), with the exception that the pre-test leak-check is mandatory

8.1.4 Sampling Train Operation. Follow the general procedures given in Method 5, section 8.5. Turn on the condenser coil coolant recirculating pump and monitor the gas entry temperature. Ensure proper gas entry temperature before proceeding and again before any sampling is initiated. It is important that the gas entry temperature not exceed 50 °C (122 °F), thus reducing the loss of toluene from the first impinger. For each run, record the data required on a data sheet such as the one shown in Method 5, Figure 5–3.

8.2 Sample Recovery. Allow the probe to cool. When the probe can be handled safely, wipe off all external particulate matter near the tip of the probe nozzle and place a cap over the tip to prevent losing or gaining particulate matter. Do not cap the probe tip tightly while the sampling train is cooling down because this will create a vacuum in the train. Before moving the sample train to the cleanup site, remove the probe from the sample train and cap the opening to the probe, being careful not to lose any condensate that might be present. Cap the impingers and transfer the probe and the impinger/condenser assembly to the cleanup area. This area should be clean and protected from the weather to reduce sample contamination or loss. Inspect the train prior to and during disassembly and record any abnormal conditions. It is not necessary to measure the volume of the impingers for the purpose of moisture determination as the method is not validated for moisture determination. Treat samples as follows:

8.2.1 Container No. 1, Probe and Impinger Numbers 1 and 2. Rinse and brush the probe/nozzle first with toluene twice and then twice again with acetonitrile and place the wash into a glass container labeled with the test run identification and ''Container No. 1.'' When using these solvents ensure that proper ventilation is available. Quantitatively transfer the liquid from the first two impingers and the condenser into Container No. 1. Rinse the impingers and all connecting glassware twice with toluene and then twice again with acetonitrile and transfer the rinses into Container No. 1. After all components have been collected in the container, seal the container, and mark the liquid level on the bottle.

8.2.2 Container No. 2, Impingers 3 and 4. Quantitatively transfer the liquid from each impinger into a glass container labeled with the test run identification and ''Container No. 2.'' Rinse each impinger and all connecting glassware twice with toluene and twice again with acetonitrile and transfer the rinses into Container No. 2. After all components have been collected in the container, seal the container, and mark the liquid level on the bottle.

Note: The contents of the fifth and sixth impinger (silica gel) can be discarded.

8.2.3 Container No. 3, Reagent Blank. Save a portion of both washing solutions (toluene/acetonitrile) used for the cleanup as a blank. Transfer 200 ml of each solution directly from the wash bottle being used and combine in a glass sample container with the test identification and ''Container No. 3.'' Seal the container, and mark the liquid level on the bottle and add the proper label.

8.2.4 Field Train Proof Blanks. To demonstrate the cleanliness of sampling train glassware, you must prepare a full sampling train to serve as a field train proof blank just as it would be prepared for sampling. At a minimum, one complete sampling train will be assembled in the field staging area, taken to the sampling area, and leak-checked. The probe of the blank train shall be heated during and the train will be recovered as if it were an actual test sample. No gaseous sample will be passed through the sampling train. Field blanks are recovered in the same manner as described in sections 8.2.1 and 8.2.2 and must be submitted with the field samples collected at each sampling site.

8.2.5 Field Train Spike. To demonstrate the effectiveness of the sampling train, field handling, and recovery procedures you must prepare a full sampling train to serve as a field train spike just as it would be prepared for sampling. The field spike is performed in the same manner as the field train proof blank with the additional step of adding the Field Spike Solution to the first impinger after the initial leak check. The train will be recovered as if it were an actual test sample. No gaseous sample will be passed through the sampling train. Field train spikes are recovered in the same manner as described in sections 8.2.1 and 8.2.2 and must be submitted with the samples collected for each test program.

8.3 Sample Transport Procedures. Containers must remain in an upright position at all times during shipment. Samples must also be stored at <4 °C between the time of sampling and concentration. Each sample should be extracted and concentrated within 30 days after collection and analyzed within 30 days after extraction. The extracted sample must be stored at 4 °C.

8.4 Sample Custody. Proper procedures and documentation for sample chain of custody are critical to ensuring data integrity. The chain of custody procedures in ASTM D4840–99 (Reapproved 2018) [e] ''Standard Guide for Sampling Chain-of-Custody Procedures'' (incorporated by reference, see § 63.14) shall be followed for all samples (including field samples and blanks).

9.0 Quality Control

9.1 Sampling. Sampling Operations. The sampling quality control procedures and acceptance criteria are listed in Table 326–2 below; see also section 9.0 of Method 5.

9.2 Analysis. The analytical quality control procedures required for this method includes the analysis of the field train proof blank, field train spike, and reagent and method blanks. Analytical quality control procedures and acceptance criteria are listed in Table 326–3 below.

9.2.1 Check for Breakthrough. Recover and determine the isocyanate(s) concentration of the last two impingers separately from the first two impingers.

9.2.2 Field Train Proof Blank. Field blanks must be submitted with the samples collected at each sampling site.

9.2.3 Reagent Blank and Field Train Spike. At least one reagent blank and a field train spike must be submitted with the samples collected for each test program.

9.2.4 Determination of Method Detection Limit. Based on your instrument's sensitivity and linearity, determine the calibration concentrations or masses that make up a representative low level calibration range. The MDL must be determined at least annually for the analytical system using an MDL study such as that found in section 15.0 to Method 301 of appendix A to part 63 of this chapter.

TABLE 326–2—SAMPLING QUALITY ASSURANCE AND QUALITY CONTROL

QA/QC criteria	Acceptance criteria	Frequency	Consequence if not met
Sampling Equipment Leak Checks.	≤0.00057 m3/min (0.020 cfm) or 4% of sampling rate, whichever is less.	Prior to, during (optional) and at the completion to sampling.	Prior to: Repair and repeat calibration. During/Completion: None, testing should be considered invalid.
Dry Gas Meter Calibration—Pre-Test (individual correction factor—Y_i).	within ±2% of average factor (individual).	Pre-test	Repeat calibration point.
Dry Gas Meter Calibration—Pre-Test (average correction factor—Y_c).	1.00 ±1%	Pre-test	Adjust the dry gas meter and recalibrate.
Dry Gas Meter Calibration—Post-test.	Average dry gas meter calibration factor agrees with ±5% Y_c.	Each Test	Adjust sample volumes using the factor that gives the smallest volume.
Temperature sensor calibration.	Absolute temperature measures by sensor within ±1.5% of a reference sensor.	Prior to initial use and before each test thereafter.	Recalibrate; sensor may not be used until specification is met.
Barometer calibration	Absolute pressure measured by instrument within ±10 mm Hg of reading with a mercury barometer or NIST traceable barometer.	Prior to initial use and before each test thereafter.	Recalibrate; instrument may not be used until specification is met.

TABLE 326–3—ANALYTICAL QUALITY ASSURANCE AND QUALITY CONTROL

QA/QC criteria	Acceptance criteria	Frequency	Consequence if not met
Calibration—Method Blanks	<5% level of expected analyte	Each analytical method blank	Locate source of contamination; reanalyze.
Calibration—Calibration Points	At least six calibration point bracketing the expected range of analysis.	Each analytical batch	Incorporate additional calibration points to meet criteria.
Calibration—Linearity	Correlation coefficient >0.995	Each analytical batch	Verify integration, reintegrate. If necessary, recalibrate.
Calibration—secondary standard verification.	Within ±10% of true value	After each calibration	Repeat secondary standard verification, recalibrate if necessary.
Calibration—continual calibration verification.	Within ±10% of true value	Daily and after every ten samples.	Invalidate previous ten sample analysis, recalibrate and repeat calibration, reanalyze samples until successful.
Sample Analysis	Within the valid calibration range	Each sample	Invalidate the sample if greater than the calibration range and dilute the sample so that it is within the calibration range. Appropriately flag any value below the calibration range.
Replicate Samples	Within ±10% of RPD	Each sample	Evaluate integrations and repeat sample analysis as necessary.
Field Train Proof Blank	≤10% level of expected analyte	Each test program	Evaluate source of contamination.
Field Train Spike	Within ±30% of true value	Each test program	Evaluate performance of the method and consider invalidating results.
Breakthrough	Final two impingers Mass collected is >5% of the total mass or >20% of the total mass when the measured results are 20% of the applicable standard. Alternatively, there is no breakthrough requirement when the measured results are 10% of the applicable standard.	Each test run	Invalidate test run.

10.0 Calibration and Standardization

Note: Maintain a laboratory log of all calibrations.

10.1 Probe Nozzle, Pitot Tube Assembly, Dry Gas Metering System, Probe Heater, Temperature Sensors, Leak-Check of Metering System, and Barometer. Same as Method 5, sections 10.1, 10.2, 10.3, 10.4, 10.5, 8.4.1, and 10.6, respectively.

10.2 High Performance Liquid Chromatograph. Establish the retention times for the isocyanates of interest; retention times will depend on the chromatographic conditions. The retention times provided in Table 10–1 are provided as a guide to relative retention times when using a C18, 250 mm x 4.6 mm ID, 5µm particle size column, a 2 ml/min flow rate of a 1:9 to 6:4 Acetonitrile/Ammonium Acetate Buffer, a 50 µl sample loop, and a UV detector set at 254 nm.

TABLE 326–4—EXAMPLE RETENTION TIMES

Retention times	
Compound	Retention time (minutes)
MI	10.0
1,6-HDI	19.9
2,4-TDI	27.1
MDI	27.3

10.3 Preparation of Isocyanate Derivatives.

10.3.1 HDI, TDI, MDI. Dissolve 500 mg of each isocyanate in individual 100 ml aliquots of methylene chloride ($MeCl_2$), except MDI which requires 250 ml of $MeCl_2$. Transfer a 5-ml aliquot of 1,2-PP (see section 7.3.8) to each solution, stir and allow to stand overnight at room temperature. Transfer 150 ml aliquots of hexane to each solution to precipitate the isocyanate-urea derivative. Using a Buchner funnel, vacuum filter the solid-isocyanate-urea derivative and rinse with 50 ml of hexane. Dissolve the precipitate in a minimum aliquot of $MeCl_2$. Repeat the hexane precipitation and filtration twice. After the third filtration, dry the crystals at 50 °C and transfer to bottles for storage. The crystals are stable for at least 21 months when stored at room temperature in a closed container.

10.3.2 MI. Prepare a 200 µg/ml stock solution of methyl isocyanate-urea, transfer 60 mg of 1,2-PP to a 100-ml volumetric flask containing 50 ml of $MeCl_2$. Carefully transfer 20 mg of methyl isocyanate to the volumetric flask and shake for 2 minutes. Dilute the solution to volume with $MeCl_2$ and transfer to a bottle for storage. Methyl isocyanate does not produce a solid derivative and standards must be prepared from this stock solution.

10.4 Preparation of calibration standards. Prepare a 100 µg/ml stock solution of the isocyanates of interest from the individual isocyanate-urea derivative as prepared in sections 10.3.1 and 10.3.2. This is accomplished by dissolving 1 mg of each isocyanate-urea derivative in 10 ml of Acetonitrile. Calibration standards are prepared from this stock solution by making appropriate dilutions of aliquots of the stock into Acetonitrile.

10.5 Preparation of Method Blanks. Prepare a method blank for each test program (up to twenty samples) by transferring 300 ml of the absorption solution to a 1,000-ml round bottom flask and concentrate as outlined in section 11.2.

10.6 Preparation of Field Spike Solution. Prepare a field spike solution for every test program in the same manner as calibration standards (see Section 10.4). The mass of the target isocyanate in the volume of the spike solution for the field spike train shall be equivalent to that estimated to be captured from the source concentration for each compound; alternatively, you may also prepare a solution that represents half the applicable standard.

10.7 HPLC Calibrations. See Section 11.1.

11.0 Analytical Procedure

11.1 Analytical Calibration. Perform a multipoint calibration of the instrument at six or more upscale points over the desired quantitative range (multiple calibration ranges shall be calibrated, if necessary). The field samples analyzed must fall within at least one of the calibrated quantitative ranges and meet the performance criteria specified below. The lowest point in your calibration curve must be at least 5, and preferably 10, times the MDL. For each calibration curve, the value of the square of the linear correlation coefficient, *i.e.,* r^2, must be ≥0.995, and the analyzer response must be within ±10 percent of the reference value at each upscale calibration point. Calibrations must be performed on each day of the analysis, before analyzing any of the samples. Following calibration, a secondary standard shall be analyzed. A continual calibration verification (CCV) must also be performed prior to any sample and after every ten samples. The measured value of this independently prepared standard must be within ±10 percent of the expected value. Report the results for each calibration standard secondary standard, and CCV as well as the conditions of the HPLC. The reports should include at least the peak area, height, and retention time for each isocyanate compound measured as well as a chromatogram for each standard.

11.2 Concentration of Samples. Transfer each sample to a 1,000-ml round bottom flask. Attach the flask to a rotary evaporator and gently evaporate to dryness under vacuum in a 65 °C water bath. Rinse the round bottom flask three times each with 2 ml of acetonitrile and transfer the rinse to a 10-ml volumetric flask. Dilute the sample to volume with acetonitrile and transfer to a 15-ml vial and seal with a PTFE lined lid. Store the vial ≤4 °C until analysis.

11.3 Analysis. Analyze replicative samples by HPLC, using the appropriate conditions established in section 10.2. The width of the retention time window used to make identifications should be based upon measurements of actual retention time variations of standards over the course of a day. Three times the standard deviation of a retention time for a compound can be used to calculate a suggested window size; however, the experience of the analyst should weigh heavily in the interpretation of the chromatograms. If the peak area exceeds the linear range of the calibration curve, the sample must be diluted with acetonitrile and reanalyzed. Average the replicate results for each run. For each sample you must report the same information required for analytical calibrations (Section 11.1). For non-detect or values below the detection limit of the method, you shall report the value as ''<'' numerical detection limit.

12.0 Data Analysis and Calculations

Nomenclature and calculations, same as in Method 5, section 6, with the following additions below.

12.1 Nomenclature.

AS = Response of the sample, area counts.
b = Y-intercept of the linear regression line, area counts.
BR = Percent Breakthrough
C_A = Concentration of a specific isocyanate compound in the initial sample, µg/ml.
C_B = Concentration of a specific isocyanate compound in the replicate sample, µg/ml.
C_I = Concentration of a specific isocyanate compound in the sample, µg/ml.
C_{rec} = Concentration recovered from spike train, µg/ml.
C_S = Concentration of isocyanate compound in the stack gas, µg/dscm
C_T = Concentration of a specific isocyanate compound (Impingers 1–4), µg/dscm
C_{spike} = Concentration spiked, µg/ml.
C_4 = Concentration of a specific isocyanate compound (Impingers 14), µg/dscm
FI_m = Mass of Free Isocyanate
FTS_{rec} = Field Train Spike Recovery
I_m = Mass of the Isocyanate
I_{mw} = MW of the Isocyanate
IU_m = Mass of Isocyanate-urea derivative
IU_{mw} = MW of the isocyanate-urea
M = Slope of the linear regression line, area counts-ml/µg.
m_I = Mass of isocyanate in the total sample
MW = Molecular weight
RPD = Relative Percent Difference
VF = Final volume of concentrated sample, typically 10 ml.
Vm_{std} = Volume of gas sample measured by the dry-gas meter, corrected to standard conditions, dscm (dscf).

Conversion from Isocyanate to the Isocyanate-urea derivative. The equation for converting the amount of free isocyanate to the corresponding amount of isocyanate-urea derivative is as follows:

12.2 Conversion from Isocyanate to the Isocyanate-urea derivative. The equation for converting the amount of free isocyante to the corresponding amount of isocyante-urea derivative is as follows:

$$IU_m = I_m \frac{IU_{mw}}{I_{mw}} \qquad \text{Eq. 326-1}$$

The equation for converting the amount of IU derivative to the corresponding amount of FL_m is as follows:

$$I_m = IU_m \frac{I_{mw}}{IU_{mw}} \qquad \text{Eq. 326-2}$$

12.3 Calculate the correlation coefficient, slope, and intercepts for the calibration data

using the least squares method for linear regression. Concentrations are expressed as the x-variable and response is expressed as the y-variable.

12.4 Calculate the concentration of isocyanate in the sample:

$$C_I = \frac{As - b}{M} \qquad \text{Eq. 326-3}$$

12.5 Calculate the total amount collected in the sample by multiplying the concentration (µg/ml) times the final volume of acetonitrile (10 ml).

$$m_I = CI \times V_f \qquad \text{Eq. 326-4}$$

12.6 Calculate the concentration of isocyanate (µg/dscm) in the stack gas.

$$C_s = \frac{M_I}{Vm_{std}} K \qquad \text{Eq. 326-5}$$

12.7 Calculate Relative Percent Difference (RPD) for each replicative sample

$$\%RPD = \left| \frac{(C_A - C_B)}{(C_A + C_B)/2} \right| x\ 100$$

Eq. 326-6

12.8 Calculate Field Train Spike Recovery

$$FTS_{rec} = \left[\frac{C_{rec}}{C_{spike}} \right] \times 100$$

Eq. 326-7

12.9 Calculate Percent Breakthrough

$$BR = \left[\frac{C_4}{C_T} \right] \times 100 \qquad \text{Eq. 326-8}$$

Where:

K = 35.314 ft^3/m^3 if Vm(std) is expressed in English units. = 1.00 m^3/m^3 if Vm(std) is expressed in metric units.

13.0 Method Performance

Evaluation of sampling and analytical procedures for a selected series of compounds must meet the quality control criteria (See Section 9) for each associated analytical determination. The sampling and analytical procedures must be challenged by the test compounds spiked at appropriate levels and carried through the procedures.

14.0 Pollution Prevention [Reserved]

15.0 Waste Management [Reserved]

16.0 Alternative Procedures [Reserved]

17.0 References

1. Martin, R.M., Construction Details of Isokinetic Source-Sampling Equipment, Research Triangle Park, NC, U.S. Environmental Protection Agency, April 1971, PB–203 060/BE, APTD–0581, 35 pp.
2. Rom, J.J., Maintenance, Calibration, and Operation of Isokinetic Source Sampling Equipment, Research Triangle Park, NC, U.S. Environmental Protection Agency, March 1972, PB–209 022/BE, APTD–0576, 39 pp.
3. Schlickenrieder, L.M., Adams, J.W., and Thrun, K.E., Modified Method 5 Train and Source Assessment Sampling System: Operator's Manual, U.S. Environmental Protection Agency, EPA/600/8–85/003/1985).
4. Shigehara, R.T., Adjustments in the EPA Nomograph for Different Pitot Tube Coefficients and Dry Molecular Weights, Stack Sampling News, 2:4–11 (October 1974).
5. U.S. Environmental Protection Agency, 40 CFR part 60, Appendices A–1, A–2, and A–3, Methods 1–5.
6. Vollaro, R.F., A Survey of Commercially Available Instrumentation for the Measurement of Low-Range Gas Velocities, Research Triangle Park, NC, U.S. Environmental Protection Agency, Emissions Measurement Branch, November 1976 (unpublished paper).

18.0 Diagrams

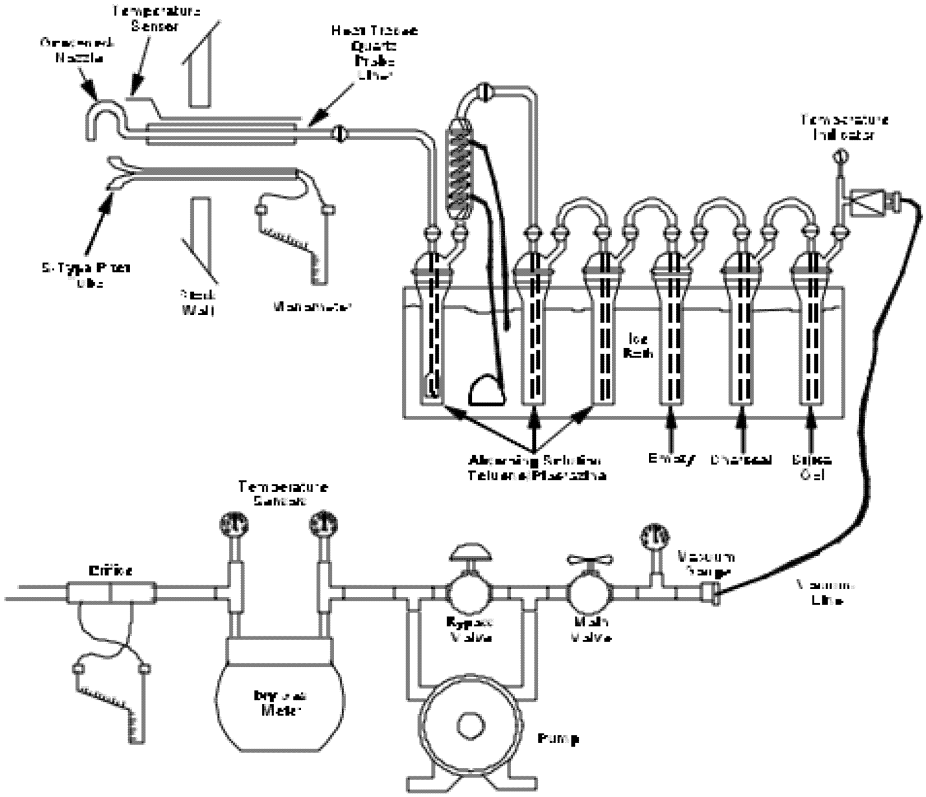

Figure 326-1—Method 326 Sampling Train

[FR Doc. 2019–01902 Filed 3–1–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL REGISTER

Vol. 84 Monday,

No. 42 March 4, 2019

Part IV

Department of Health and Human Services

42 CFR Part 59

Compliance With Statutory Program Integrity Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

[HHS–OS–2018–0008]

RIN 0937–ZA00

Compliance With Statutory Program Integrity Requirements

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, HHS. Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Office of Population Affairs (OPA), in the Office of the Assistant Secretary for Health, issues this final rule to revise the regulations that govern the Title X family planning program (authorized by Title X of the Public Health Service Act) to ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning and related statutory requirements. Accordingly, OPA amends the Title X regulations to clarify grantee responsibilities under Title X, to remove the requirement for nondirective abortion counseling and referral, to prohibit referral for abortion, and to clarify compliance obligations with state and local laws. In addition, Title X regulations are amended to clarify access to family planning services where an employer exercises a religious or moral objection. Finally, Title X regulations are amended to require physical and financial separation to ensure clarity regarding the purpose of Title X and compliance with statutory program integrity provisions, and to encourage family participation in family planning decisions, as required by Federal law.

DATES: *Effective date:* This rule is effective on May 3, 2019.

Compliance date: Compliance with the physical separation requirements contained in § 59.15, is required March 4, 2020.

Compliance with the financial separation requirements contained in § 59.15 is required by July 2, 2019. Until that date, the Department will expect grantees to comply with either § 59.15 or the ''Separation'' section of the guidance at 65 FR 41281, 41282.

Compliance with §§ 59.7 and 59.5(a)(13) is required by July 2, 2019.

Compliance for reporting, assurance, and provision of service in §§ 59.5(a)(12) and (13) as it applies to all required reports, 59.5(a)(14), (b)(1) and (8), 59.13, 59.14, 59.17, and 59.18 is required by July 2, 2019.

Compliance for all other requirements of this final rule is required by the effective date, that is, by May 3, 2019.

FOR FURTHER INFORMATION CONTACT: The Office of the Assistant Secretary for Health (OASH) at (202) 690–7694, *ASH@hhs.gov,* or by mail at 200 Independence Avenue SW, Washington, DC 20201

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary and Background
A. Executive Summary
1. Purpose
2. Summary of the Major Provisions
a. Clear Financial and Physical Separation
b. Ensure Transparency for Legal and Ethical Use of Taxpayer Dollars Among Subrecipients
c. Nondirective Pregnancy Counseling Permitted, Not Required
d. Referral for Abortion as a Method of Family Planning Prohibited, No Longer Required
e. Sexual Abuse Reporting Requirements Training and Protocols
f. Family Participation in Family Planning Decisionmaking
g. Expanded Review and Selection Criteria
h. Formal Revocation of Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients Rule
3. Summary of Costs, Savings and Benefits of the Major Provisions
B. Background
II. Statutory Authority, Overview, Analysis, and Response to Public Comments
A. General Comments
B. To what programs do these regulations apply? (42 CFR 59.1)
C. Definitions (42 CFR 59.2)
1. Definition of Advanced Practice Provider
2. Definition of Family Planning
3. Definition of Grantee
4. Definition of Low Income Family
5. Definition of Program or Project
6. Definition of Subrecipient
D. Who is eligible to apply for a family planning services grant or contract? (42 CFR 59.3)
E. What requirements must be met by a family planning project? (42 CFR 59.5)
1. Broad Range of Acceptable and Effective Family Planning Methods (42 CFR 59.5(a)(1))
a. Acceptable and Effective Methods and Services
b. Projects Required To Provide a Broad Range of Family Planning Methods and Services, But Participating Entities May Offer a Limited Number of Family Planning Methods and Services
c. Listing Particular Services in the Broad Range of Family Planning Services That May Be Provided
2. Projects Shall Not Provide, Promote, Refer For, or Support Abortion as a Method of Family Planning (42 CFR 59.5(a)(5))
3. Removal of the Requirement for Consultation (42 CFR 59.5(a)(10))
4. Promotion of Access to Comprehensive Primary Health Services (42 CFR 59.5(a)(12))
5. Title X Transparency (42 CFR 59.5(a)(13)
6. Encouragement of Family Participation (42 CFR 59.5(a)(14))
7. Provide for Medically Necessary Services (42 CFR 59.5(b)(1))
8. Provide for Coordination and Referral, Consistent With Prohibition on Referral for Abortion (42 CFR 59.5(b)(1))
F. Criteria for Selection of Grantees (42 CFR 59.7)
G. Confidentiality (42 CFR 59.11)
H. Standards of Compliance With Prohibition on Abortion (42 CFR 59.13)
I. Requirements and Limitations With Respect to Post-Conception Activities (42 CFR 59.14)
1. Prohibition on Referral For, and Encouragement, Promotion, Advocacy, Support, and Assistance of, Abortion as a Method of Family Planning (42 CFR 59.14(a), 59.5(a)(5), and 59.16(a))
2. Information About Prenatal Care, Use of Permitted Information To Refer for Abortion, and Examples (42 CFR 59.14(b)(1), (c), and (e))
3. Emergency Care and Medically Necessary Information (42 CFR 59.14(b)(2) and 59.14(d))
J. Maintenance of Physical and Financial Separation (42 CFR 59.15)
K. Prohibition on Activities That Encourage, Promote or Advocate for Abortion (42 CFR 59.16)
L. Compliance With Reporting Requirements (42 CFR 59.17)
M. Appropriate Use of Funds (42 CFR 59.18)
N. Transition Provisions (42 CFR 59.19)
III. Economic/Regulatory Impact and Paperwork Burden
A. Introduction and Summary
1. Executive Orders 12866 and 13563 and the Congressional Review Act
2. Regulatory Flexibility Act (RFA)
3. Unfunded Mandates Reform Act
4. Federalism
5. Summary of the Final Rule
B. Analysis of Economic Impacts
1. Need for Regulatory Action
2. Affected Entities
3. Estimated Costs
a. Learning the Rule's Requirements
b. Training
c. Assurance Submissions
d. Documentation of Compliance
e. Monitoring and Enforcement
f. Physical Separation
g. Encouraging Parental Involvement in Family Planning Services
4. Estimated Benefits
a. Upholding and Preserving the Purpose and Goals of the Title X Program
b. Patient/Provider Benefits and Protections
C. Analysis of Regulatory Alternatives
D. Executive Order 13771
E. Regulatory Flexibility Analysis
F. Assessment of Federal Regulation and Policies on Families
G. Paperwork Reduction Act

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this rule is to finalize, with changes in response to public comments, revisions to the Title X family planning regulations proposed on June 1, 2018.[1] This rule, promulgated pursuant to the Department's authority,[2] will ensure compliance with, and enhance implementation of, the statutory requirement that none of the funds appropriated for Title X may be used in programs where abortion is a method of family planning, as well as related statutory requirements. In addition, the rule ensures that grantee responsibilities, referral requirements, and documentation obligations are clear under the Title X program. The rule also clarifies that provision of family planning services under Title X may be available under the good reason exception at the discretion of the project director for women denied coverage for contraceptives if the sponsor of their health plan exercises a religious or moral exemption recognized by the Department.[3] The rule protects vulnerable populations by ensuring Title X providers comply with State reporting requirements. And, consistent with Federal law, the rule encourages family participation in family planning decisions of minors except where the minor is or may be the victim of child abuse or incest. To ensure the best applicants are chosen, the rule expands review and selection criteria to include provisions that will help evaluate applicants' adherence to statutory requirements and goals. In addition, the rule formally repeals the 2016 amendments to the Title X eligibility requirements, which were nullified by a joint resolution of disapproval, under the Congressional Review Act, signed by the President. This rule will protect the integrity of the Title X program, pursuant to congressional purpose, to offer a broad range of family planning methods and services and improve the quality of programs that specifically provide support in this area.

2. Summary of the Major Provisions

a. Clear Financial and Physical Separation

This rule finalizes requirements that ensure clear physical and financial separation between a Title X program and any activities that fall outside the program's scope. This physical and financial separation will ensure compliance with the statutory requirement that Title X funding not support programs where abortion is a method of family planning—and is consistent with the plain text of Section 1008, legislative history, and case law. In particular, the rule protects against the intentional or unintentional co-mingling of Title X resources with non-Title X resources or programs by amending the Department's regulation finalized on July 3, 2000, (the ''2000 regulations''), which required no physical separation and only limited financial separation.[4] This rule will require Title X providers to maintain physical and financial separation from locations which provide abortion as a method of family planning.

Together, these changes address several concerns of the Department. They address concerns over the fungibility of Title X resources and the potential use of Title X resources to support programs where, among other things, abortion is a method of family planning. They address the potential for ambiguity between approved Title X activities and non-Title X activities and services, which creates significant risk for public confusion over the scope of Title X services, including whether Title X funds are allocated for, or spent on, non-Title X services, including abortion-related purposes. And they address the concern that Title X resources could facilitate the development of, and ongoing use of, infrastructure for non-Title X activities. The Department seeks to protect Title X (and Title X funds) as the only discrete, domestic, Federal grant program focused solely on the provision of cost-effective family planning methods and services. The final rule thus requires physical and financial separation to protect the statutory integrity of the Title X program, to eliminate the risk of co-mingling or misuse of Title X funds, and to prevent the dilution of Title X resources.

b. Ensure Transparency for Legal and Ethical Use of Taxpayer Dollars Among Subrecipients

This rule facilitates the legal and ethical use of taxpayer dollars by implementing reporting requirements with respect to the use of Title X funds. The 2000 regulations do not require grantees to submit significant information to the government about their subrecipients, referral agencies, or other partners to whom Title X funds may flow. This lack of reporting can be a significant barrier to the Department's ability to ensure Title X funds are directed only to Title X activities. Accordingly, the final rule requires that Title X grant applicants include, as part of their applications, a list of all planned subrecipients, detailed descriptions of the extent of services and collaboration with subrecipients, and a clear explanation of how the applicant, if successful, would conduct an oversight program with respect to its subrecipients.[5] The final rule defines a subrecipient as any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. Consistent with grant reporting requirements, grantees must regularly report and demonstrate their own compliance, as well as ensure the compliance of their subrecipients with all statutory and regulatory requirements. The Department will also require grantees to establish a plan to ensure that they and their subrecipients comply with all applicable State reporting requirements of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking, adequately train staff regarding such requirement and include protocols that ensure such minors are provided counseling on how to resist attempts to coerce them into engaging in sexual activities; and will commit to preliminary screening of such minors. The final rule establishes that the continuation of funding for grantees and subrecipients is contingent on their demonstration to the satisfaction of the Secretary that the statutory and regulatory requirements of Title X have been met. To ensure proper accounting of Title X funds, the Secretary may

[1] *See* Compliance with Statutory Program Integrity Requirements, 83 FR 25502 (proposed June 1, 2018) (to be codified at 42 CFR part 59).

[2] For a detailed discussion regarding statutory authority, *see infra* Section II. Statutory Authority, Overview, Analysis, and Response to Public Comments.

[3] *See* Religious exemptions in connection with coverage of certain preventive services, 45 CFR 147.132 (2019); *see also* Moral exemptions in connection with coverage of certain preventive health services, 45 CFR 147.133 (2019).

[4] *See* Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 42 CFR part 59, which omit any mention of physical or financial separation; *see also* Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 FR 41270, 41275–41276 (July 3, 2000) where the Department discusses its decision in the 2000 regulation to require financial separation, while choosing to not require physical separation.

[5] To further ensure program transparency (and ensure a seamless continuum of care), applicants and grantees are also required to provide certain information about agencies or individuals providing referral services and their collaborations with such referral agencies and individuals.

review grantee and subrecipient records to ensure regulatory compliance.

To increase program integrity, the Department will also increase various monitoring and reporting requirements. Under the final rule, grantees will be required to receive approval for any change in the use of grant funds, and to fully account for and justify charges against the Title X grant. The final rule will also increase monitoring requirements to better ensure appropriate billing practices. And because the 2000 regulations offer scant guidance on the Anti-lobbying Act and appropriations law provisions applicable to Title X, this final rule will require Title X grantees to provide assurances satisfactory to the Secretary that they both understand and agree to the prohibition against lobbying and political activity in the Title X project.

The Department believes that these changes will ensure that OPA has the information necessary to determine whether Title X projects, grantees, and subrecipients are compliant with the statutory and regulatory provisions applicable to the program.

c. Nondirective Pregnancy Counseling Permitted, Not Required

This rule finalizes several regulatory provisions designed to ensure that the requirements of the Title X regulations are consistent with certain laws that protect the conscience rights of individuals and entities who decline to perform, participate in, or refer for, abortions. The 2000 regulations require Title X projects to provide abortion referral [6] and nondirective counseling on abortion, if requested. The Department believes this requirement is inconsistent with federal conscience laws and, as discussed below with respect to the referral provision, also violates Section 1008. With respect to conscience, the regulatory requirement to counsel on abortion, if requested, conflict with HHS enforced statutes protecting conscience in health care, including the Church Amendment,[7] Coats-Snowe Amendment [8] and the Weldon Amendment [9] for individual and institutional entities who object. The Department acknowledged this conflict in the 2008 conscience regulations, stating that its ''current regulatory requirement that grantees must provide counseling and referrals for abortion upon request . . . is inconsistent with the health care provider conscience protection statutory provisions and this regulation.'' Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 FR 78072, 78087 (Dec. 19, 2008). The proposed rule in this rulemaking similarly recognized the ongoing conflict between the 2000 regulation and conscience protections. In the 2008 provider conscience regulation, the Department stated that OPA was ''aware of this conflict with the statutory requirements [of the Church, Coats-Snowe, and Weldon Amendments] and, as such, would not enforce this Title X regulatory requirement on objecting grantees or applicants,'' *id.,* but was unable to directly address the Title X requirements, given the rulemaking context. The Department believes that it is appropriate and necessary to revise the Title X regulatory text to eliminate the provisions which are inconsistent with the health care conscience statutory provisions.[10]

Under the final rule, the Title X regulations no longer require pregnancy counseling, but permits the use of Title X funds in programs that provide pregnancy counseling, so long as it is nondirective. Nondirective pregnancy counseling is the meaningful presentation of options where the physician or advanced practice provider (APP) [11] is ''not suggesting or advising one option over another.'' 138 Cong. Rec. H2822, H2826, 1992 WL 86830. Section 1008 and its legislative history offers additional clarity specifically as to abortion, where the physician or APP cannot engage in ''promoting, encouraging, or advocating abortion.'' *Id.* at H2829. Nondirective counseling does not mean that the counselor is uninvolved in the process or that counseling and education offer no guidance, but instead that clients take an active role in processing their experiences and identifying the direction of the interaction. In nondirective counseling, the Title X physicians and APPs promote the client's self-awareness and empower the client to be informed about a range of options, consistent with the client's expressed need and with the statutory and regulatory requirements governing the Title X program. In addition, the Title X provider may provide a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some (but not the majority) of which may provide abortion in addition to comprehensive primary care.

Accordingly, this final rule eliminates the abortion counseling requirements in the 2000 regulations, consistent with the Department's interpretation of federal conscience laws and Section 1008. This rule continues to allow nondirective pregnancy counseling, as discussed in more detail below.

[6] Referral for abortion is discussed in the next section.

[7] The Church Amendments, among other things, prohibit certain HHS grantees from discriminating in the employment of, or the extension of staff privileges to, any health care professional because they refused, because of their religious beliefs or moral convictions, to perform or assist in the performance of any lawful sterilization or abortion procedures. The Church Amendments also prohibit individuals from being required to perform or assist in the performance of any health service program or research activity funded in whole or in part under a program administered by the Secretary contrary to their religious beliefs or moral convictions. *See* 42 U.S.C. 300a–7.

[8] The Coats-Snowe Amendment bars the federal government and any State or local government that receives federal financial assistance from discriminating against a health care entity, as that term is defined in the Amendment, who refuses, among other things, to provide referrals for induced abortions. *See* 42 U.S.C. 238n(a).

[9] The Weldon Amendment was added to the annual 2005 health spending bill and has been included in subsequent appropriations bills. *See* Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, sec. 507(d), 132 Stat. 348, 764; Consolidated Appropriations Act, 2017, Public Law 115–31, Div. 507(d), 131 Stat. 135, 562. The Weldon Amendment bars the use of appropriated funds on a federal agency or programs, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not, among other things, refer for abortions.

[10] In the preamble to the 2000 regulations, the Department addressed a comment that the requirement to provide options counseling ''should not apply to employees of a grantee who object to providing such counseling on moral or religious grounds,'' and rejected it, contending that it is not necessary because, under the Church Amendments, ''grantees may not require individual employees who have such objections to provide such counseling,'' but ''in such cases the grantees must make other arrangements to ensure that the service is available to Title X clients who desire it.'' 65 FR 41270, 41274 (July 3, 2000). But the evidence collected in the Department's 2018 conscience proposed rule, 83 FR 25502, 25506 (June 1, 2018), suggests that neither grantees nor their employees may know of the requirements of the Church Amendment. More importantly, the Department's 2000 analysis failed to consider that the Coats-Snowe Amendment (and the subsequently passed Weldon Amendment) protects institutional health care providers from discrimination by federal programs, including Title X, on the basis of their refusal to counsel or refer for abortion and, thus, that ''under section 245 of the Public Health Service Act and the Weldon Amendment, the Department cannot . . . enforce 42 CFR 59.5(a)(5) against an otherwise eligible grantee or applicant who objects to the requirement to counsel on or refer for, abortion.'' 73 FR at 78088.

[11] Under this final rule, nondirective counseling may be provided by physicians and advanced practice providers. As discussed in detail below, the final rule defines ''advanced practice providers'' as including physician assistants and advanced practice registered nurses.

d. Referral for Abortion as a Method of Family Planning Prohibited, No Longer Required

This rule finalizes the revocation of the requirement that Title X projects refer for abortion, and finalizes the prohibition against using Title X funds to refer for abortion as a method of family planning, or to perform, promote, or support abortion as a method of family planning. Although the 2000 regulations require Title X programs to refer for abortion when requested by a client,[12] the Department no longer believes that the requirement is appropriate or permissible. Like the counseling requirement, the Department believes the referral requirement is in conflict with federal conscience protections, such as the Church, Coats-Snowe, and Weldon Amendments, for individual and institutional entities which object, and is finalizing the proposal to remove that requirement from the regulations. Furthermore, the Department believes that, in most instances when a referral is provided for abortion, that referral necessarily treats abortion as a method of family planning. The Department believes both the referral for abortion as a method of family planning, and such abortion procedure itself, are so linked that such a referral makes the Title X project or clinic a program one where abortion is a method of family planning, contrary to the prohibition against the use of Title X funds in such programs. The Department, thus, views such abortion referrals in the Title X project as a violation of Section 1008, which prohibits the use of Title X funds in programs where abortion is a method of family planning. *See* 42 U.S.C. 300a–6. Even if the referral requirement was not in tension with these statutes, the Department believes that such a requirement may deter qualified providers from applying for Title X grants or participating in Title X projects, and may introduce ambiguity about the use of Title X funds to support abortion as a method of family planning. Accordingly, this final rule removes the requirement that Title X funded entities refer for abortion, and prohibits Title X projects from referring for abortion as a method of family planning, or from performing, promoting, referring for, or supporting abortion as a method of family planning.

e. Sexual Abuse Reporting Requirements Training and Protocols

This rule finalizes the requirement that Title X programs and providers comply with State and local sexual abuse reporting requirements, as well as the requirement for training and clinic protocols on such requirements and related issues, to ensure that Title X providers meet the applicable statutory and regulation reporting requirements of the Title X program and treat the survivors of sexual abuse and assault with dignity and compassion, without hindering State and local efforts to prevent sexual abuse.[13] Section 59.11 of the 2000 regulations, on the confidentiality of Title X records, provides that personal information may not be disclosed absent consent by the individual, except to provide treatment, or as required by law, ''with appropriate safeguards for confidentiality.'' *See* 42 CFR 59.11. To ensure that Title X grantees and subrecipients comply with applicable reporting requirements, the Department clarifies in this final rule that concerns about confidentiality of information may not be used as a rationale for noncompliance with such reporting laws.

As established in § 59.17 of this final rule, Title X providers are required to comply with all State and local laws regarding notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, or human trafficking. The 2000 regulations permit the use of confidential information obtained by project staff to comply with State and local reporting requirements,[14] but do not expressly address the appropriations law requirement to report certain crimes, nor impose a federal obligation on Title X grantees and subrecipients to comply with State reporting or notification requirements. The final rule clarifies that Title X grantees and subrecipients must comply with State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and/or human trafficking. To ensure compliance with that obligation and to ensure the appropriate care for such patients, their safety, and their personal empowerment, the final rule requires Title X grantees and subrecipients to have in place a plan to implement the specific reporting requirements that apply to them in their State (or jurisdiction), as well as to provide for annual training for all personnel with respect to these requirements, how such reports are to be made, and appropriate interventions, strategies, and referrals.

As part of prevention, protection, and risk assessment efforts, grantees and subrecipients are required to include in such plans, protocols to identify individuals who are victims of sexual abuse or targets for underage sexual victimization and to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce minors into engaging in sexual activities.[15] Title X projects are also required, under this final rule, to conduct a preliminary screening of any minor who presents with an STD, pregnancy, or suspicion of abuse, in order to rule out victimization of the minor. Section 59.17 requires grantees and subrecipients to maintain records that would identify, among other things, the age of any minor clients served, the age of their sexual partner(s) where required by State law, and what reports or notifications were made to appropriate State agencies. The Department will use this documentation to ensure appropriate compliance with State notification laws.

f. Family Participation in Family Planning Decisionmaking

This rule finalizes requirements that Title X providers encourage appropriate family participation in family planning decisions, as required by Federal law.[16] The Title X statute itself requires the encouragement of such family

[12] *See* 42 CFR 59.5; 65 FR 41270, 41278 (July 3, 2000).

[13] *See* Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115–245, Div. B, sec. 208, 132 Stat. 2981, 3070 (''HHS Appropriations Act 2019'') (emphasizing the Congressional expectation that ''Notwithstanding any other provision of law, no provider of services under title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.'').

[14] *See* 42 CFR 59.11.

[15] The annual appropriations laws also impose on Title X recipients the obligation to provide ''counseling to minors on how to resist attempt to coerce minors into engaging in sexual activities.'' *See* HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. 2981, 3070; Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, sec. 207, 132 Stat. 348, 736; Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, sec. 207, 131 Stat. 135, 538; Consolidated Appropriations Act, 2016, Public Law 114–113, Div. H, sec. 207, 129 Stat 2242, 2620. Such requirement is also consistent with Title X's direction to provide special services for adolescents.

[16] Title X requires that, ''[t]o the extent practical, entities which receive grants or contracts under this subsection shall encourage familiy [sic] participation in projects under this subsection.'' 42 U.S.C. 300(a). Congress also includes a rider in HHS's annual appropriations act that provides that ''[n]one of the funds appropriated in this Act may be made available to any entity under title X of the PHS Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services.'' HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. 2981, 3070; Consolidated Appropriations Act 2018, Public Law 115–141, Div. H, sec. 207, 132 Stat. 348, 736.

participation to the extent practical,[17] and the Department will continue to enforce compliance with this provision. An appropriations rider specifically emphasizes that grantees encourage family participation ''in the decision of minors to seek family planning services.'' [18] Accordingly, to ensure compliance with these requirements and the policy underlying them, the Department will also require specific recordkeeping with respect to such encouragement for minors. To ensure compliance with the requirement that Title X projects encourage family participation in the decision of minors to seek family planning services, § 59.5(a)(14) requires Title X projects to document in each minor's medical records the specific actions taken to encourage such family participation or the specific reason why such family participation was not encouraged. Consistent with the revision to the unemancipated minor example in the definition of ''low income family'' that the Department finalizes in this rule, documentation of such encouragement is not required if the Title X provider documents in the medical record that (1) the minor is suspected to be the victim of child abuse or incest and (2) it has, if permitted or required by applicable State or local law, reported the situation to the relevant authorities. These requirements are sensitive to confidentiality issues as well as reporting requirements for abuse.

g. Expanded Review and Selection Criteria

This rule updates and expands the review and scoring criteria applicable to grant applications, to ensure the criteria serve as a meaningful instrument to assess the quality of the applicant and the application. The 2000 Title X regulations set forth application review criteria that give the Department significant flexibility in determining awards but lack rigor, making it possible for less qualified applicants to garner high scores and affording the Department little help in selecting strong Title X grantees. The amended and revised § 59.7 ensures that successful applicants both meet the statutory requirements of the Title X program and are adequately responsive to the statutory goals and purposes of the Title X program. Under this rule, any grant application that does not clearly address how the proposal will satisfy the requirements of the rule would not proceed to the competitive review process, but would be deemed ineligible for funding.

The Department will explicitly summarize each requirement of the Title X regulations (or include the entire regulation) within the Funding Announcement and will require applicants to describe how they affirmatively comply, or would affirmatively comply with each provision. Once an applicant successfully demonstrates such affirmative compliance with the Title X regulations (a yes/no issue), the Department will consider each applicant competitively according to the criteria set forth in the regulation. The first criterion ensures that the project offers a broad range of acceptable and effective family planning methods and services and does not use abortion as a method of family planning. The second criterion looks at the relative need of the applicant and whether the applicant will make rapid and effective use of the funds. The third criterion takes into account the number of patients being served, while also considering the availability of family planning services in the proposed area. The fourth criterion considers the extent to which the services are needed in that local area and if the applicant proposes innovative ways to provide services to unserved or underserved patients. These provisions better achieve the statutory requirements and goals of Title X and increase competition and rigor among applicants, encouraging broader and more diverse applicants and better ensuring the selection of quality applicants.

h. Formal Revocation of Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients

This rule formally revokes the 2016 amendments to the Title X eligibility requirements. In 2016, the Department finalized a rule that amended Title X eligibility requirements, prohibiting any grantee/recipient making service subawards as part of its Title X project, from excluding an entity from receiving a subaward for reasons other than its ability to provide Title X services. Compliance With Title X Requirements by Project Recipients in Selecting Subrecipients, 81 FR 91852, 91859–91860 (Dec. 19, 2016) (adding paragraph (b) to 45 CFR 59.3) (the ''2016 regulation''). The Department's stated reason for issuing the rule was to respond to new approaches to competing or distributing Title X funds that were being employed by several States. *Id.* at 91858–91859. The 2016 regulation took effect on January 18, 2017, but was nullified under the Congressional Review Act on April 13, 2017, when the President signed House Joint Resolution 43. *See* Public Law 115–23, 131 Stat. 89. Consistent with the joint resolution of disapproval, this rule repeals the 2016 regulation and, thus, permits States and other Title X grantees freely to select Title X subrecipients so long as they comply with the statutory, regulatory, and policy provisions in the funding announcement.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and benefits	Costs
Clear Financial and Physical Separation	The purpose of this provision is to ensure that the regulatory language is consistent with Section 1008 of the Public Health Service Act. The Department estimates no specific economic savings from finalizing this part of the rule. However, the Department expects the quality of Title X services to improve as Title X funds are focused and prioritized according to the statutory parameters.	The Department estimates that there will be transition costs where certain other programs that shared facilities with Title X programs must now establish separate physical facilities. After receiving public comments, the Department estimates physical compliance costs to be $36.08 million.

[17] The Department notes that, although section 1001 of the PHS Act states that ''[t]o the extent *practicable,* entities which receive grants or contracts under this subsection shall encourage family participation in projects assisted under this subsection,'' PHS Act § 1001(a), in the U.S. Code, 42 U.S.C. 300(a), the word ''practical'' is used in the provision. The Department believes that the two words are intended to have the same meaning and uses the two words interchangeably when discussing the statutory requirement.

[18] *See* HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. 2981, 3070.

Provision	Savings and benefits	Costs
Ensure Transparency for Legal and Ethical Use of Taxpayer Dollars among Subrecipients.	The purpose of this provision is to ensure that Title X funds are allocated and accounted for both by Title X grantees and by the Department. The Department estimates no specific cost savings from finalizing this part of the Rule. However, the Department expects that enhanced accounting and monitoring will result in more effective use of Title X resources.	The Department estimates, in part based on public comments, that the cost of implementing additional reporting and training requirements will be $8.53 million. Medical and health services managers will spend an average of four hours each year to complete reports regarding information related to subrecipients, and referral agencies and individuals involved in the grantee's Title X project at each grantee and subrecipient. The labor cost will be $254,000 each year ($52.58 per hour × 4 hours × 1,208 grantees and subrecipients).
Nondirective Pregnancy Counseling Permitted, Not Required.	The purpose of this provision is to remove the requirement that providers provide pregnancy counseling, particularly, abortion counseling. Eliminating the requirement to counsel for abortion, and allowing non-directive pregnancy counseling in general, will relieve burdens by giving projects flexibility, and relieve burdens on conscience that some entities and individuals experienced from complying with the previous requirement, or provide more flexibility for applicants that otherwise might not have applied due to the burdens on conscience of the previous requirement. This rule will also reduce the regulatory burden associated with monitoring and Title X providers for compliance with the abortion counseling requirement.	The Department estimates no costs from finalizing this part of the rule.
Abortion Referral Prohibited, No Longer Required.	The purpose of this provision is to remove the requirement for, and institute a prohibition against abortion referral in the Title X program. Eliminating the requirement to refer for abortion will relieve burdens on conscience that some entities and individuals experienced from complying with the previous requirement, and provide more flexibility for applicants that otherwise might not have applied due to the burdens on conscience of the previous requirement. This rule will also reduce the regulatory burden associated with monitoring and regulating Title X providers for compliance with the abortion referral requirement.	The Department estimates no costs associated with removing the requirement for abortion referral. The addition of a prohibition against abortion referral will involve no additional monitoring costs, as current mechanisms in place are expected to be sufficient.
Sexual Abuse Reporting Requirements Training and Protocols.	The purpose of this provision is to ensure providers are complying with State and local sexual abuse reporting requirements. The Department estimates no specific economic savings from finalizing this part of the rule. However, the Department expects Title X providers will be more informed about State and local reporting requirements, and therefore, will protect vulnerable populations.	The Department estimates that individuals involved with delivering family planning services would require an average of 4 hours of training in the first year following publication of this rule. In subsequent years, the Department assumes that this new information would be incorporated into existing training requirements, resulting in no incremental burden. As a result, using wage information provided in Table 2, this would imply costs of $2.71 million in the first year following publication of a final rule in this rulemaking.
Family Participation in Family Planning Decisionmaking.	The purpose of this provision is to ensure compliance with the requirement by Congress to encourage family participation in family planning decisionmaking, and to include this requirement in regulation. The Department estimates no specific economic savings from finalizing this part of the rule. However, the Department expects Title X providers will encourage parent and child communication as is expected under Federal law.	The Department estimates that complying with the requirement to encourage family participation will result in 75% (600,000) of adolescent patients' medical records requiring appropriate documentation. As a result, using wage information provided, this would imply costs of $2.0 million in the each year following publication of a final rule in this rulemaking.

Provision	Savings and benefits	Costs
Expanded Review and Selection Criteria	The purpose of this provision is to increase the quality and expand the specificity of grant application review criteria. The Department estimates no specific economic savings from finalizing this part of the rule. However, these criteria will better achieve the statutory requirements and goals of Title X by increasing competition and rigor among applicants, encouraging broader and more diverse applicants and better ensuring the selection of quality applicants.	
Formal Revocation of Compliance with Title X Requirements by Project Recipients in Selecting Subrecipients Rule.	The purpose of this provision is to finalize the revocation of the 2016 regulation. The Department estimates no specific economic savings from finalizing this part of the rule as it is a formal repeal of a change that was nullified by under the Congressional Review Act.	The Department estimates no costs from finalizing this part of the rule as it is a formal repeal of a change that was nullified by joint resolution of disapproval under the Congressional Review Act that was signed by the President.

B. Background

Title X of the Public Health Service Act, 42 U.S.C. 300 through 300a–6, was enacted in 1970 by Public Law 91–572, 84 Stat. 1504. As amended, it authorizes the Secretary of Health and Human Services, among other things, ''to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).'' 42 U.S.C. 300(a).

Presently, the Title X program funds approximately 90 public health departments and community health, family planning, and other private nonprofit agencies through grants, supporting delivery of family planning services at almost 4,000 service sites.[19] As a program designed to provide voluntary family planning services, the Title X program should help men, women, and adolescents make healthy and fully informed decisions about starting a family and determining the number and spacing of children.

Section 1008 of the Act contains the following prohibition, which has not been altered since it was enacted in 1970: ''None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.'' 42 U.S.C. 300a–6. The Conference Report described the purpose of this provision as follows:

> It is, and has been, the intent of both Houses that funds authorized under this legislation be used only to support preventive family planning services, population research, infertility services, and other related medical, information, and educational activities. The conferees have adopted the language contained in section 1008, which prohibits the use of such funds for abortion, in order to make clear this intent.

H.R. Rep. No 91–1667, at 8–9 (1970) (Conf. Rep.). Later Congresses have, through annual appropriations provisions, reiterated aspects of this requirement, for example, by adding that ''amounts provided to said [voluntary family planning] projects under such title shall not be expended for abortions.'' *See, e.g.,* HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. at 3070.

Since it originally created the Title X program in 1970, Congress has, from time to time, imposed additional requirements on it, including the following:

- Requirement that ''all pregnancy counseling shall be nondirective.''[20]
- Obligation to ensure that Title X funds ''shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.''[21]
- Requirement that Title X (1) projects provide distinct services for adolescents;[22] (2) service providers encourage family participation in family planning services including, but not limited to, those for minors;[23] (3) grantees certify to the Secretary that they ''provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.''[24]
- Condition that, ''[n]otwithstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.''[25]

Title X authorizes the Secretary to promulgate regulations governing the program. 42 U.S.C. 300a–4. In the preamble to the proposed rule, the Department explained that, since 1971, it has repeatedly exercised rulemaking authority with respect to the Title X program. The Department began issuing regulations implementing Title X, including section 1008, in 1971. *See* 36 FR 18465 (Dec. 15, 1971). Although those regulations, and revised regulations issued in 1980, 45 FR 37436 (Jun. 3, 1980), as well as guidelines promulgated in 1981, prohibited Title X projects from providing abortion as a method of family planning, they did not

[19] Fowler et al., *Family Planning Annual Report: 2017 National Summary* (Aug. 2018), *https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf.*

[20] *See* Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, sec. 104, 110 Stat. 1321 (1996) (''Omnibus Appropriations Act 1996''); HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. at 3070–71.

[21] HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. at 3071.

[22] *See* 42 U.S.C. 300(a) (requirement to provide ''a broad range of acceptable and effective family planning methods and services (including . . . services for adolescents)'').

[23] *See* Omnibus Budget Reconciliation Act of 1981, Public Law 97–35, sec. 931(b)(1), 95 Stat. 357, 570 (1981) (amending Section 1001(a) of the Public Health Service Act to require that ''[t]o the extent practical, entities which receive grants or contracts . . . shall encourage family participation in projects assisted under this subsection.''); 42 234 U.S.C. 300(a); Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495 (''HHS Appropriations Act 1998''); HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[24] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495; HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[25] HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 208, 132 Stat. at 3090.

provide further guidance on the application of that prohibition.

On February 2, 1988, the Secretary of Health and Human Services promulgated Title X regulations (the ''1988 regulations'') to give specific program guidance regarding the statutory prohibition on the use of Title X funds in programs where abortion is a method of family planning. *See* Statutory Prohibition on Use of Appropriated Funds in Programs Where Abortion is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects, 53 FR 2922 (Feb. 2, 1988). The 1988 regulations had several key features to support compliance with the statutory prohibition. To more effectively implement section 1008, the regulations prohibited Title X projects from counseling or referring project clients for abortion as a method of family planning; required grantees to separate their Title X project—physically and financially—from prohibited abortion-related activities; and established compliance standards for family planning projects under Title X to specifically prohibit certain actions that promote, encourage, or advocate abortion as a method of family planning, such as the use of project funds for lobbying for abortion, developing and disseminating materials advocating abortion, or taking legal action to make abortion available as a method of family planning. *See* 53 FR 2945.

The 1988 regulations were upheld on both statutory and constitutional grounds by the United States Supreme Court in *Rust* v. *Sullivan,* 500 U.S. 173 (1991). In *Rust,* the Supreme Court rejected claims that the regulations violated the Administrative Procedure Act (APA), the First Amendment, the Fifth Amendment, or the Title X statute. Regarding the APA, the Court applied *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council,* 467 U.S. 837 (1984), reasoning that ''substantial deference'' was owed ''to the interpretation of the authorizing statute by the agency authorized with administering it.'' 500 U.S. at 184. Accordingly, it reaffirmed that ''[a]n agency is not required to 'establish rules of conduct to last forever,' but rather 'must be given ample latitude to 'adapt [its] rules and policies to the demands of changing circumstances.'' 500 U.S. at 186–187. The Court declined to view the regulations skeptically because they represented a change in policy; instead, the Court noted that it ''has rejected the argument that an agency's interpretation 'is not entitled to deference because it represents a sharp break with prior interpretation' of the statute in question.'' *Id.* The Court concluded that the regulations' ''program integrity'' requirements—the portions of the regulations mandating separate facilities, personnel, and records—were ''based on a permissible construction of the statute and are not inconsistent with congressional intent.'' *Id.* at 188. Accordingly, the Court ''defer[red] to the Secretary's reasoned determination that the program integrity requirements are necessary to implement the prohibition.'' *Id.* at 190.

The Court further upheld the prohibition on abortion counseling and referral, as well as the requirement of physical and financial program separation, as consistent with the First Amendment. *Id.* at 192–198. The Court held the ''Government has no constitutional duty to subsidize an activity merely because the activity is constitutionally protected and [Congress] may validly choose to fund childbirth over abortion and 'implement that judgment by the allocation of public funds' for medical services relating to childbirth but not to those relating to abortion.'' *Id.* at 201 (internal quotations omitted). The Court concluded that the regulations were ''a permissible construction of Title X.'' *Id.* at 203.

The 1988 regulations were operative until February 5, 1993, when President Clinton suspended them pursuant to a Presidential Memorandum, The Title X ''Gag Rule'', 58 FR 7455 (Feb. 5, 1993), and the Department issued a proposed rule, Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 FR 7464 (Feb 5, 1993), that it finalized seven years later as the 2000 regulations. *See* 65 FR 41270 (July 3, 2000). The 2000 regulations essentially returned to the 1981 regulations (with one revision), which eliminated the provisions of the 1988 regulations that (1) prohibited Title X projects from counseling or referring project clients for abortion as a method of family planning; (2) required grantees to separate their Title X project physically and financially from any abortion activities; and (3) implemented compliance standards for family planning projects under Title X that specifically prohibit certain actions designed broadly to promote or encourage abortion as a method of family planning, such as the use of project funds to lobby for abortion, to develop and disseminate materials advocating abortion, or to take legal action to make abortion available as a method of family planning. While a contemporaneous notice stated that more than separate bookkeeping entries and allocation of funds was necessary to separate Title X project activities from non-Title X abortion activities, that notice nevertheless discussed and approved shared facilities, staff, and records, as long as costs were pro-rated and properly allocated. *See* Provision of Abortion-Related Services in Family Planning Service Projects, 65 FR 41281, 41282 (July 3, 2000). The 2000 regulations also required that Title X providers offer nondirective counseling on, and referral for, abortion at the request of a Title X client, despite the statutory prohibition on funding programs where abortion is a method of family planning and the adoption of the Coats-Snowe Amendment in 1996 and Weldon Amendment in 2005, which prohibited the federal government and State and local governments that receive federal financial assistance from discriminating against health care entities that refuse, among other things, to refer for abortion.

On December 19, 2016, the Department finalized a rule that amended Title X eligibility requirements, requiring that no grantee making subawards for the provision of services as part of its Title X project prohibit an entity from receiving a subaward for reasons other than its ability to provide Title X services. 81 FR 91852, 91860 (Dec. 19, 2016). The Department's stated reason for issuing the rule was to respond to new approaches to competing or distributing Title X funds that were being employed by several States. The 2016 regulation took effect on January 18, 2017, but was nullified under the Congressional Review Act, when the President signed the Joint Resolution of Disapproval, on April 13, 2017. *See* Title X Requirements by Project Recipients in Selecting Subrecipients, Public Law 115–23, 131 Stat. 89 (April 13, 2017).

On June 1, 2018, the Department published a proposed rule in the **Federal Register**, through which it solicited public comments on proposed changes to the 2000 Title X regulations and the formal revocation of the 2016 regulation in accordance with the Joint Resolution of Disapproval. *See* 83 FR 25502, 25504–25505 (June 1, 2018). The Department believes the provisions of this final rule provide much needed clarity regarding the Title X program's role as a family planning program that is statutorily forbidden from paying for abortion and funding programs/projects where abortion is a method of family planning. The Department believes that the 2000 regulations fostered an environment of ambiguity surrounding appropriate Title X activities. This uncertainty was reflected in many of the public comments that argued Title X

should support statutorily prohibited activities, such as abortion. This rule rectifies the ambiguity created by the 2000 regulations. Specifically, this rule:

- Clearly delineates a bright line between Title X and non-Title X activities;
- provides grantees direction on how to ensure that no Title X funds are expended where abortion is a method of family planning;
- increases the ability of applicants to receive funding for innovative projects that propose to serve underserved and unserved populations; and
- offers additional protection to patients who may be victims of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking.

II. Statutory Authority, Overview, Analysis, and Response to Public Comments

The Department provided a 60-day public comment period for the proposed rule that closed on July 31, 2018. The Department received over 500,000 public comments,[26] which are posted at *www.regulations.gov.* After considering the comments, the Department finalizes the proposed rule with the changes discussed below. In this preamble, the Department discusses the public comments, its responses, and the text of the final rules.

The Department proposed to revise the authorities cited for the regulations at 42 CFR part 59, subpart A, from ''42 U.S.C. 300a–4'', to ''42 U.S.C. 300 through 300a–6''. Some commenters support the Department's authority to modify Title X regulations. Other commenters contend that the Department does not have authority to make various changes. The Department has legal authority under section 1006 of the Public Health Service Act, 42 U.S.C. 300a–4, to promulgate and amend regulations to implement the Title X family planning program, and sections 1001 through 1008 of the Public Health Service Act (42 U.S.C. 300 through 300a–6) include substantive provisions which the Department implements through such regulations. The Department has repeatedly exercised its authority to issue regulations to guide Title X grantees in carrying out the program. Section 1006 of the Act states that ''[g]rants and contracts made under this title shall be made in accordance with such regulations as the Secretary may promulgate,'' and section 1001 also specifies that the Secretary shall by regulation specify certain rights to apply for grants or contracts. The grant of regulatory rulemaking authority in section 1006 is sufficient authority to support all of the requirements adopted through this final rule. However with respect to various details of these final rules, the Department also relies on section 1008 and other directives throughout the Title X statute, as well as appropriations provisos and riders governing the Title X program. The final rule is designed to refocus the Title X program on its statutory mission—the provision of voluntary, preventive family planning services specifically designed to enable individuals to determine the number and spacing of their children—while clarifying that women must be referred for appropriate, medically necessary care identified during preconception screening and for prenatal care services, since such care is important for both the health of the women and for healthy pregnancy and birth. The Department believes this final rule provides appropriate guidance for compliance with such requirements.

Therefore, the Department finalizes, without change, its proposed revision to the authorities cited for 42 CFR part 59, subpart A.

Comments supporting or challenging the Department's authority to make particular changes are discussed in more detail in the relevant sections below.

A. General Comments

While many comments were specific to certain sections of the proposed rule, a sizeable number were more general in nature, or commented on portions of the preamble, including content in the background, the need for change, and the statutory authorities sections. Those comments are summarized here, together with responses by the Department. Many related comments are addressed in greater detail further below, within the discussion of specific provisions of the regulation.

Comments: Many commenters affirm the accuracy of the historical record summarized by the Department in the proposed rule. This includes the long-standing prohibition on promoting abortion in the Title X program, the Supreme Court's upholding of the 1988 regulations in *Rust* v. *Sullivan,* the Court's reaffirmation of Congress's general intent for Title X to have a preconception focus, the legal precedent for the government to favor childbirth over abortion (for example, *Harris* v. *McRae,* 448 U.S. 297 (1980)), the continued bipartisan support for the Title X statute, and the various supplemental requirements imposed by Congress on the Title X program. Other commenters also contend that, since *Roe* v. *Wade,* 410 U.S. 113 (1973), Title X grantees have unlawfully treated abortion as a method of family planning despite statutory prohibitions and that the 2000 regulations facilitate such activity in violation of the Title X statute. Additional commenters recall the history, purpose, importance, and value of Title X as the sole federal program dedicated to funding family planning services for low income individuals, including the provision of birth control, cancer screening, sexually transmitted disease (STD) testing and treatment, and other preventive care.

The Department received comments expressing diverse and conflicting views on the proposed rule. Many commenters support the language of the rule as proposed, so as to prevent taxpayer dollars from being used to pay for activities related to abortion, contrary to the Title X statute, and to provide the necessary transparency to assure Title X funds are not used for abortion or abortion-related costs. Other commenters assert that proposed changes could reduce access to services, especially for the most vulnerable populations. Some commenters note that the proposed rule closely mirrors the 1988 regulations, while others object to the proposed rule's provisions, particularly on certain abortion referrals, and the similar but broader provisions in the 1988 regulations, and point out that those provisions were never fully implemented. Some commenters support the proposed rule as providing much needed clarification to ensure adherence to the original intent of Title X and to correct the regulations that were issued in 2000. Other commenters contend that the proposed rule is unnecessary, unjustified, unethical, and was proposed without evidence of need.

Some commenters raised legal objections to the rule. Several comments contend the Department's proposed rule is contrary to congressional intent, violative of State sovereignty, and inconsistent with the First Amendment rights of Title X grantees and the Fifth Amendment rights of women. These commenters assert that women have a constitutional right to abortions, and health care workers have a responsibility to counsel individuals on the full scope of family planning options.

Commenters assert that the proposed changes create ethical and legal risks,

[26] This includes attachments and over 40 mass mailing or internet comment generating campaigns, which accounted for more than 480,000 of the comments. The **Federal Register** docket lists only 205,000 comments; however a significant number of comments were submitted in batches to *www.regulations.gov.*

fail to follow professional standards of care for health professionals, and violate conditions associated with federal grant funding under section 330 of the Public Health Service Act.[27] Commenters request clarification on how broadly reporting requirements would apply, specifically regarding referral agencies. They assert that Federally Qualified Health Centers (FQHC), funded under Section 330 of the Public Health Safety Act, are already required to provide significant data reporting, including patient demographics, financial indicators, and clinical quality. Commenters believe that the proposed Title X reporting requirements would be potentially redundant with the existing section 330 reporting requirements. Commenters also argue section 330 requires FQHCs to provide ''voluntary family planning'' services. This rule, they argue, creates a conflict with that requirement by reducing the family planning options, and potentially reduces the performance of FQHCs by restricting their supplementary Title X funding.

Others argue that the proposed rule would make it difficult to meet national performance measures for the Title V Maternal and Child Health Services Block Grant, which serve as a measure of our country's progress on adolescent annual preventive medical visits. Still other commenters argue the proposed rule violates the APA on multiple grounds, including that the rule is arbitrary and capricious, and they assert that the Department has not provided adequate reasons for its rulemaking by examining the relevant data and articulating a satisfactory explanation for its action, including a rational connection between the facts found and the choices made. Several commenters urge the Department to withdraw the proposed rule. Some commenters contend the rule is not legally supportable and that, if the Department finalizes the rule, it will be challenged in court.

In contrast, other commenters argue that the proposed rule closely tracks the 1988 regulations, which were upheld on both statutory and constitutional grounds by the Supreme Court. Those commenters argue that the proposed rule is just as constitutional now as it was then, and observe that many other cases have affirmed the principle that the government is not obligated to fund or facilitate abortions.

Numerous commenters state that the Department has spent much time and effort to craft a solution where there is no problem to be addressed. They claim Title X has never funded abortions, and Title X providers fully understand what the statutes and 2000 regulations require. They state that examples of the misuse of Title X funds are not well founded. Several commenters state that, under the comment filing deadline of July 31, 2018, they were unable to evaluate the full extent of the impacts of the Notice of Proposed Rule Making (NPRM) on affected communities. These commenters requested that the Department extend the comment period an additional 60 days, or to October 1, 2018. They contend this extension would provide the Department more time to hear from impacted populations on changes to Title X. One commenter contends their extension request was due to the Department rushing the publication of the proposed rule, and engaging in insufficient public engagement with stakeholders prior to the release of the rulemaking. Another commenter mentions they were requesting an extension because they experienced issues with submitting their comments electronically.

Response: The Department notes that there is, generally, a common understanding regarding the history and the purpose of the Title X program, together with the sharp diversity of opinion regarding the need for revisions to the 2000 regulations. The Department appreciates the emphasis many comments place on Title X's role in caring for low income individuals by providing a broad range of family planning methods and services. The Department concludes these final rules will contribute to more clients being served, gaps in service being closed, and improved client care that better focuses on the family planning mission of the Title X program. The Department expects these positive outcomes, in part, because the Department believes (1) program parameters will be more clear; (2) new applicants will apply to serve unserved or underserved patients and/or less concentrated population areas because the review and selection criteria will no longer skew in favor of heavily populated areas; (3) new providers who previously were unable to participate in Title X projects due to conscience concerns with the 2000 regulations will be free to apply for a Title X grant or to participate in a Title X project; (4) Title X providers will be more likely to provide comprehensive primary care services or refer to primary health providers who can fulfill non-Title X needs in close proximity to the clinics, furthering overall health care of patients; and (5) the broad and clear definition for ''family planning'' will enable grantees to better provide a broad range of family planning methods and services to meet the needs and desires of more patients.

The Department believes that the final rule represents a better interpretation of the statutory provisions applicable to the Title X program than the 2000 Regulations. The rule permits and will encourage better and closer compliance with these legal obligations on the part of grantees and their subrecipients. The Department agrees with comments stating that the proposed rule is necessary to protect the integrity of the Title X program, and the Department has authority to take such action, as discussed above and supported by case law.[28] The Spending Clause of the Federal Constitution provides Congress authority to spend monies and to impose conditions and requirements with respect to the expenditures of funds,[29] and it has exercised this authority to create the Title X program and impose conditions upon it. The Department has, in turn, exercised its legal authority [30] to issue regulations to guide Title X grantees in carrying out the program. The rule will ensure adherence to the statutory provisions adopted by Congress for the Title X program.

The Department agrees with comments that section 1008 establishes a broad prohibition on funding, directly or indirectly, activities that treat abortion as a method of family planning.[31] The Department also agrees with comments that the 2000 regulations are inconsistent with that interpretation insofar as they require referral for abortion as a method of family planning, allow the use of funds for building infrastructure that could be used for abortion services, and do not require clear physical separation between Title X activities and abortion-related services.[32] The Department

[27] *See* 42 U.S.C. 254b.

[28] *See Rust,* 500 U.S. at 193.

[29] Art. 1, sec. 8, cl. 1.

[30] *See* 42 U.S.C. 300a–4.

[31] *See* 42 U.S.C. 300a–6.

[32] As described in the preamble to the 1988 regulations, 53 FR at 2923, prior to issuance of any regulations pursuant to Title X, the Department had, since 1972, interpreted section 1008 not only as prohibiting the provision of abortion, but also as prohibiting Title X projects from in any way promoting or encouraging abortion as a method of family planning. Further, based on the legislative history, the Department had also, since 1972, interpreted section 1008 as requiring that the Title X program be ''separate and distinct'' from any abortion activities of a grantee. However, in such interpretations, the Department generally took the view that if activity did not have the immediate effect of promoting abortion, or which did not have the principal purpose or effect of promoting abortion, it was permitted in a project. *See* GAO, No. HRD–82–106, Restrictions on Abortion and

Continued

notes that the 2000 regulations also do not ensure transparency and accountability in the use of taxpayer funds since they fail to require grantees to provide the Department with information about subrecipients, to ensure monitoring for potential misuse of funds and for compliance with federal laws (including a Title X-specific appropriations provision) that prohibit the use of taxpayer funds for political activity or lobbying. Finally, the 2000 regulations prescribe inadequate grant application review criteria for selecting grantees of Title X funds who will comply with all of these requirements.

The Department believes that the final rule is a reasonable interpretation of the Title X statute and applicable laws in light of the express statutory terms, legislative history, and case law regarding the implementation and enforcement of provisions such as section 1008. The express terms in section 1008 reasonably support the Department's conclusion that there must be a separation between Title X projects and funds and any project where abortion is a method of family planning. *See* 42 U.S.C. 300a–6. The express terms of section 1008 also reflect the congressional purpose that Title X primarily has a preconception focus and should fund and, thereby, encourage preconception services. *See Rust,* 500 U.S. at 190 (''It is undisputed that Title X was intended to provide primarily prepregnancy preventive services.''). This focus on preconception care generally excludes payment for postconception care and services, though it can allow the provision of information and counseling in a postconception context, or access to postconception services outside the Title X project, if Title X's restrictions concerning abortion as a method of family planning are maintained. It is, thus, no surprise that the Supreme Court concluded that the 1988 regulations' ''program integrity'' requirements, which are substantially similar to the ones adopted in this final rule—including the portions of the regulations mandating separate facilities, personnel, and records—were ''based on a permissible construction of the statute and are not inconsistent with congressional intent.'' *Id.* at 188. The Court noted that, ''if one thing is clear from the legislative history, it is that Congress intended that Title X funds be kept separate and distinct from abortion-related activities. . . . Certainly, the Secretary's interpretation of the statute that separate facilities are necessary, especially in light of the express prohibition of § 1008, cannot be judged unreasonable.'' *Id.* at 190. The Court ''defer[red] to the Secretary's reasoned determination that the program integrity requirements are necessary to implement the prohibition.'' *Id.* The Department now reaffirms that reasoned determination and reaches similar conclusions here.

The Department disagrees with commenters who contend the proposed rule (or this final rule) violates the Constitution and the intent of Title X. The Supreme Court rejected similar constitutional challenges to the 1988 regulations. As an initial matter, it upheld the statutory limitation of Title X funds to programs where abortion is not a method of family planning, concluding that ''[t]here is no question but that the statutory prohibition contained in § 1008 is constitutional'' because Congress ''may 'make a value judgment favoring childbirth over abortion, and . . . implement that judgment by the allocation of public funds.' '' *Id.* at 192 (internal citations omitted; ellipsis in original). The Court further explained that the provisions in the 1988 regulations barring counseling and referral were consistent with the First and Fifth Amendments. *Id.* at 193–94, 203. The Department believes the Court's analysis encompasses, and is equally applicable to, the provisions of this final rule for similar reasons.

The Department disagrees with commenters contending the proposed rule, to the extent it is finalized here, infringes on the legal, ethical, or professional obligations of medical professionals. Rather, the Department believes that the final rule adequately accommodates medical professionals and their ethical obligations while maintaining the integrity of the Title X program. In general, medical ethics obligations require the medical professional to share full and accurate information with the patient, in response to her specific medical condition and circumstance. Under the terms of this final rule, a physician or APP may provide nondirective pregnancy counseling to pregnant Title X clients on the patient's pregnancy options, including abortion. Although this occurs in a postconception setting, Congress recognizes and permits pregnancy counseling within the Title X program, so long as such counseling is nondirective. The permissive nature of this nondirective pregnancy counseling affords the physician or APP the ability to discuss the risks and side effects of each option, so long as this counsel in no way promotes or refers for abortion as a method of family planning. It permits the patient to ask questions and to have those questions answered by a medical professional. Within the limits of the Title X statute and this final rule, the physician or APP is required to refer for medical emergencies and for conditions for which non-Title X care is medically necessary for the health and safety of the mother or child.

The Department appreciates comments expressing concern about administrative reporting burdens on FQHCs who receive funding under both Section 330 and Title X. However, different federal programs often have different reporting and other requirements, depending on the specific statutory requirements and constraints. The fact that some federal grant programs may require more (or less) to qualify for funding is an appropriate reflection of Congressional direction. The Department is mindful of the administrative burden when establishing requirements for federal grant programs and seeks, as possible, to impose substantially the same administrative requirements on grant programs. However, it is under no obligation to impose the same requirements for multiple grant programs; rather, it is guided by the statutory requirements placed by Congress regarding each individual federal grant program. To the extent that requirements overlap, the Department believes that no additional burden results because the information can be readily shared within the grantee organization. Where the Title X program imposes additional requirements, these additional requirements are the result of specific statutory requirements applicable to the Title X program. The Department believes that these additional requirements are reasonable in light of those specific statutory requirements and the Department's need to ensure compliance with such requirements.

The Department also believes that concerns that Title X will conflict with Section 330's voluntary family planning requirements are unfounded. This final rule continues the historical Title X emphasis that family planning must be voluntary—the definition of ''family planning'' adopted by the final rule and, thus, applicable to the Title X program explicitly states that ''family planning methods and services are never to be coercive and must always be strictly voluntary.'' This final rule also confirms the statutorily mandate that a ''broad range'' of family planning methods and services be available under Title X. This requirement also supports the voluntary

Lobbying Activities in Family Planning Programs Need Clarification, at 22 (Sept. 24, 1982), *https://www.gao.gov/assets/140/138760.pdf.*

nature of family planning by providing a variety of methods and services so that the individual patient can make an informed choice, based on her own lifestyle and needs. To the extent that limitations are imposed on the Title X program (*e.g.,* abortion provisions), the Department has carefully designed these to enforce explicit statutory mandates applicable to Title X. However, the Department intends to continue emphasizing the broad range of family planning methods and services as a way to fulfill the various family planning needs of patients who visit the many Title X clinics across the nation. Thus, the Department finds that section 330 and Title X are complementary in this respect.

The Department does not agree that the final rule will impede the ability of States and jurisdictions to meet the national performance measure (NPM) for annual adolescent preventive well visits for the Title V Maternal and Child Health Services Block Grant. Some commenters contend that any limitation on a patient's ability to access affordable health care at their preferred site of care for family planning services or to meet with the provider of their choice for preventive health care will impede States' ability to meet their goals for the well-woman visit NPM and the adolescent well-visit NPM for Title V. But by encouraging Title X projects to offer either comprehensive primary health care services onsite or have a robust referral linkage with primary health care providers who are in close proximity to the Title X site, the Department believes this final rule should reinforce States' ability to meet their goals for well-woman and adolescent well-visit NPMs. Furthermore, the Department does not believe that the rule will limit the ability of individuals to access affordable health care; thus, achievement of the NPM will remain unaffected by the changes in regulation. The Title X program currently provides services to adolescents and will continue to provide these services.

The Department agrees with comments stating that demonstrated abuses of Medicaid funds do not necessarily mean Title X grants are being abused and did not make that argument in the proposed rule. Rather, the Department believes that examples of abuse in other Federal programs help illustrate the need for clarity with respect to permissible and impermissible activities in connection with the Title X program and Title X funds, especially where the 2000 regulations foster confusion and ambiguity.[33] Title X is a grant program where funds are disbursed before completion of the service, increasing the possibility of intentional or unintentional misuse of funds. Appropriate accountability standards are particularly appropriate in the case of grant programs such as Title X.

The Department's reasons for deciding to revise the 2000 regulations go beyond evidence regarding abuses of Medicaid funds by entities that are also Title X grantees or subrecipients, and are discussed in more detail below. These additional reasons include the Department's view that Title X grantees must be financially transparent and accountable throughout the grant disbursement process, rather than only after the grant is spent. The Department has a compelling interest in ensuring that, from the moment of disbursal, Title X funds are used only for permissible activities under the Title X statute,[34] rather than condoning after-the-fact correction and bookkeeping adjustments. The Department disagrees with some commenters who characterize the government's pursuit of this interest as ''restricting abortion rights''; the Supreme Court rejected similar arguments and challenges to similar provisions in the 1988 regulations. *See Rust,* 500 U.S. at 177–178 (upholding similar Title X ''program integrity'' requirements).

The Department also seeks to remedy the potential for confusion, under the 2000 regulations, about whether Title X funds can be, or are being used, in a project where abortion is a method of family planning. It does so by finalizing the rule to strengthen the requirements for financial separation and to preclude shared physical space and staff with respect to abortion. It also does so by improving grant monitoring, including fiscal and internal controls, to prevent the misuse of taxpayer funds. The Title X program is not unique in the need for such grant monitoring to identify and prevent such misuse. However, particularly because providing abortion as a method of family planning has been statutorily prohibited,[35] and abortion is a source of contentious public debate, the Department believes improved accountability measures are a useful and responsible action that will expand taxpayers' trust in the Title X program.

In response to commenters who contend the rule will be challenged in court, the Department believes the Supreme Court's decision in *Rust* provides broad support for the approach taken in this rule. Although the rule differs in some respects from the 1988 regulations upheld in *Rust,* some of those differences arise from the Department's desire to implement statutory provisions that did not exist at the time the 1988 regulations were adopted. Other differences, such as the permission for nondirective pregnancy counseling—which implements an appropriations rider that was adopted as early as 1996 [36] and has been regularly included in HHS's appropriations through fiscal year 2019—are more permissive than the 1988 regulations and less susceptible to the type of challenges that plaintiffs brought (unsuccessfully) in *Rust.* Other changes concern issues not directly addressed in *Rust,* but plainly supported by the Department's discretion to implement the program as set forth in Title X and applicable statutes. The Department believes that each component of the rule is legally supportable, individually and in the aggregate. To the extent a court may enjoin any part of the rule, the Department intends that other provisions or parts of provisions should remain in effect.

The Department disagrees with commenters who state that the 60-day comment period was insufficient. The APA does not have a minimum time period for comments, and 60-day comment periods are used for large numbers of very significant rules, including rules that contain far more complicated and complex proposed requirements. The comment period closed 60 days after publication of the proposed rule in the **Federal Register** on June 1, 2018, but the proposed rule went on display at the Office of the Federal

[33] ''. . . [A]udits have found overbilling . . . improper practices resulting in significant Title XIX-Medicaid overpayment . . . [and] ''unbundling'' or ''fragmentation'' billing schemes related to pre-abortion examinations, counseling visits, and other services performed in conjunction with an abortion, and improper billing for the abortions themselves.'' *See* Foster, *Profit. No Matter What, 2017 Report on Publicly Available Audits of Planned Parenthood Affiliates and State Family Planning Programs,* Charlotte Lozier Institute Special Report Series 3 (Jan. 4, 2017), *https://lozierinstitute.org/profit-no-matter-what (summarizing evidence from publicly available audits).* These examples of abuse illustrate the need to clarify any confusion or ambiguity that may cause or add to the problems uncovered by the auditors.

[34] 42 U.S.C. 300a–6.

[35] *Id.*

[36] Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, 110 Stat. 1321, 1321–221 (stating that ''amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective, and that such amounts shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.''). The 2019 Appropriations Act contains the same directive.

Register on June 1, 2018 and on the Department's website on May 22, 2018. The comment period provided ample time for the submission of over 500,000 comments by a variety of interested parties, including extensive comments by a number of entities. Those comments offer a broad array of perspectives on the full range of issues raised in the proposed rule. After reviewing the public comments and the requests for additional time, the Department does not believe that extending the comment period is or was necessary for the public to receive sufficient notice of, and opportunity to comment on, the proposed rule. Nor is there anything in the statutory provisions governing the Title X program that would have required additional outreach outside of the public notice and comment process and the comment period. Consequently, the Department concludes that the comment period was legally sufficient and is not extending the comment period.

B. To what programs do these regulations apply? (42 CFR 59.1)

Summary of changes: The original language of the 2000 regulations at § 59.1 remains intact. The proposed rule proposed to add that, unless otherwise noted, Title X program requirements and regulations would apply equally to grantees and their subrecipients and that grantees would be responsible for ensuring that the entire project, which includes all subrecipients, complies with the Title X regulations. With certain exceptions, the proposed rule also provided that the regulatory requirements of Title X would apply equally to any contracts established under Section 1001 to carry out a Title X project. The Department finalizes the proposed changes to § 59.1 with slight technical changes to clarify the language regarding the requirements for grantees and subrecipients.

Comments: Some commenters question the need for the proposed changes. They state that the Department is not lacking information about subrecipients, as the Department already publishes a directory listing all subrecipients online. Some commenters contend that previously, the Department's legal relationships have been with Title X grantees concerning project operations only, not with subrecipients.

Several commenters state that the rule gives unprecedented information and regulatory authority to the Department regarding Title X grantees and subrecipients. Some commenters assert that the regulations attempt to give the Department unchecked discretion to disqualify applications. Several commenters contend the proposed rule would impose burdensome and redundant bureaucratic responsibilities on grantees and would limit the participation of certain providers. Some commenters object to the application of the rule to subrecipients, contending it will impose unacceptable burdens on subrecipients and drive qualified providers from Title X projects.

One commenter believes that treating grants and contracts equally will circumvent fair contracting rules, expediting allocation of funds to organizations and programs that do not submit applications as part of a competitive procurement or that will not be required to follow program regulations, including basic eligibility guidelines. The commenter states that, if implemented, this change could drastically alter the landscape of Title X providers, potentially allowing, among other things, for-profit organizations and health care providers that do not meet the highest standards of quality care to be awarded federal funds through a non-competitive process. One commenter states the proposed rule does not adequately discuss the regulatory or economic impact of applying the same requirements of contracts as family planning grants to entities, as contract and grant regulations differ.

One comment states that the proposed rule does not address whether Title X funds used for contracts would offset funds used for grants.

Response: The Department disagrees with commenters who contend that the Department already has sufficient information about subrecipients. Although an online directory lists subrecipients, important information about the grant project is not reported at a granular level. The Department does not know the scope of services provided by individual subrecipients, nor the degree of compliance with statutory and regulatory requirements by individual subrecipients. The Department maintains it is reasonable and appropriate to require additional transparency in these areas to ensure accountability for, and compliance with, the statutory integrity provisions applicable to the Title X program. Moreover, it is quite common for regulatory requirements to flow down from grantees to subrecipients; this final rule simply makes that expectation explicit.

The Department also does not agree with some commenters contending that these regulations are unnecessary, redundant, or overly burdensome. As discussed more below, the Department has a duty to ensure that Title X funds are spent in accordance with statutory requirements; that duty applies equally to Title X funds used by grantees and subrecipients. The final rule helps the Department fulfill that duty and thereby to ensure the proper accounting of Title X funds. The Department believes there has been insufficient transparency and accountability in the use of taxpayer funds because grantees have not been required to provide the Department with sufficient information about subrecipients, to ensure monitoring for potential misuse of funds, or to address express statutory program integrity provisions and limitations (including a Title X specific appropriations provision) that, among other things, prohibit the use of taxpayer funds for political activity or lobbying. The final rule will redress these insufficiencies and improve the transparency and accountability that surrounds the use of Title X funds.

The Department concludes that the final rule appropriately requires that the program integrity provisions of Title X family planning program apply to projects whether they are established by grants or contracts and to any entity receiving Title X funds. The Department disagrees that the application of Title X regulations to the execution of contracts is an exercise of improper or unprecedented regulatory authority. Title X authorizes the Secretary to carry out the Title X program by entering into contracts with, or issuing grants to, public or private nonprofit entities and to promulgate regulations governing grants and contracts issued in the program. 42 U.S.C. 300(a), 300a–4. Thus, the Department has the authority to issue regulations governing the program, including provisions that apply statutory requirements both to grantees and contractors, and subrecipients of Title X funds. With respect to subrecipients, since grantees in most instances do not directly provide Title X services, the only way to ensure compliance with the statutory and regulatory requirements is to require the inclusion of provisions in contracts with, or grants to, subrecipients that require such compliance. Such flow-down requirements are a commonly used mechanism in the Department's grant programs to ensure that the programs are properly implemented. The Department believes that ensuring Title X funds are expended by subrecipients consistent with the statutory and regulatory parameters is a responsibility that all Title X grantees reasonably assume when they extend the financial benefits of the program to another party.

The Department disagrees with commenters that challenge the Department's oversight role in the proposed rule. Title X grantees must ensure adequate oversight of Title X funds, including the use of those funds by subrecipients. The statutory restrictions imposed on the use of Title X funds cannot be avoided by distributing the funds to subrecipients. The Department is committed to ensuring all rules governing Title X funds are applied to both primary grantees and subrecipients. The Department does not agree with commenters who state that the administrative cost of ensuring that subrecipients are compliant with Title X is overly burdensome. Although there may be additional costs involved with these oversight measures, specifying that grantees are responsible for ensuring the compliance of their subrecipients does not add an additional requirement; it merely makes more explicit the fact that grantees are already responsible for ensuring the compliance of their Title X projects with the statutory and regulatory requirements applicable to Title X projects. The specific oversight measures required by this final rule are reasonable and necessary to ensure such compliance with the Title X requirements and proper accountability of Title X funds. The costs associated with those measures are detailed below.

The Department disagrees that the rule will exclude qualified providers from providing Title X services since any eligible organization may apply to provide Title X services, so long as it complies with the requirements set forth in the statute, related regulations, and the funding announcement. The Department disagrees with commenters who suggest oversight will hinder the participation of health centers, except to the extent that they are not compliant with Title X requirements. An organization that qualifies under Title X to provide statutorily appropriate services may also provide non-Title X services, so long as they do so in a manner that complies with the Title X regulations. The Department believes that the provisions of the final rule will result in expanded preconception family planning options available to individuals consistent with the Title X program's explicit mandate.

The Department has considered the comments that express concern about the proposed language that treats Title X contracts and grants equally, but concludes that a plain reading of the statute supports that approach. Title X authorizes the Secretary to award grants and/or enter into contracts to establish and operate voluntary family planning projects—and then authorizes the Secretary to adopt regulations to implement the Title X program.[37] The Department interprets this grant of authority to afford it flexibility in choosing the vehicles to implement the Title X statute, but not to allow funding vehicles that avoid the requirements of the Title X program. Grants and contracts are entered into under different general procedures and are governed by different sets of procedural law. Title X projects, however, whether implemented by grant or contract, must comply with applicable substantive requirements of the Title X statute, which these regulations implement.

Accordingly, regardless of whether the Department enters into a grant or contract, requirements of the Title X program shall apply, except for §§ 59.4, 59.8, and 59.10. For example, the Department interprets section 1008 of Title X to require certain restrictions concerning abortion referrals, and physical and financial separation between Title X activities and activities not permitted under the Title X statute. That interpretation would apply to project activities whether they are undertaken by grant or by contract. This regulatory provision applying certain sections of this rule to contracts is necessary to ensure consistency in the implementation and enforcement of Title X statutory program integrity provisions if a project is implemented through the issuance of a contract.

The Department notes comments that draw distinctions between grants and contracts in the general regulatory system and how they serve different purposes. The Department recognizes these differences exist, but for reasons stated above, believes it necessary to ensure the basic requirements of the Title X program are consistent. Title X authorizes the Secretary to enter into contracts, not just grants, to implement the program.[38] The Department believes it is necessary to treat contracts and grants similarly for both grantees (or, in the case of contracts, contractors) and subrecipients or subcontractors.

The Department disagrees with commenters who contend the proposed rule would circumvent ordinary procurement procedures. The Department's purpose in adding the provision on its ability to carry out a Title X program/project by contract was not to evade or avoid the substantive requirements imposed by Title X or these regulations—the Department, for example, could not contract with a for-profit entity to carry out a Title X program or project because that would be inconsistent with 42 U.S.C. 300(a)—but to confirm that contracts to implement the Title X program must be consistent with, and implement, the substantive requirements entailed in these regulations, including those related to the prohibition on the use of funds for projects where abortion is a method of family planning. If the Department enters into contracts, it would do so based on other rules generally applicable to contracts, except as specified in the Title X statute or these regulations. Thus, for example, any contracts issued under Title X would continue to be competitive to the extent required by law and regulation. To make that clear, the proposed rule would provide that certain sections of part 59 subpart A would not apply to contracts because those sections address processes specifically applicable to grants and grant applications. The substantive requirements of the other sections of the subpart, in contrast, would apply to Title X projects or programs, regardless of whether they are carried out by grant or contract.[39]

Accordingly, the Department expects both grantees and contractors to ensure that Title X funds are spent on statutorily appropriate activities. The proposed rule and this final rule help to ensure that this expectation is met by formalizing those requirements and that process.

One commenter had inquired about how the issuance of a contract to implement a Title X project would affect Title X grants. Since the funds for the program are fixed by appropriations, funds used for contracts in a given fiscal year would not be used for grants, and vice versa. Thus, Title X funds used for contracts would be offset from funds used for grants, as stated in the proposed rule.

C. Definitions (42 CFR 59.2)

1. Definition of Advanced Practice Provider

Summary of changes: The 2000 regulations did not define ''advanced practice provider,'' and the Department had not proposed such a definition in the proposed rule. However, as a result

[37] *See* 42 U.S.C. 300(a), 300a–4(a).

[38] *See* 42 U.S.C. 300(a).

[39] Although the Department had proposed that § 59.3 would not be applicable to contractors carrying out a Title X project, after further consideration, and in light of the public comments, the Department now believes that such contractors should be required to comply with § 59.3. Accordingly, the Department does not include that section in the list of regulatory provisions that would not apply to entities who have contracted with the Department to implement a Title X project. This is discussed in more detail below in response to comments concerning § 59.3.

of comments on the type of medical professional who could provide nondirective counseling and referrals under the proposed rule, as discussed in greater detail below, the Department has determined that, in addition to medical doctors, advanced practice providers (APPs) may provide nondirective counseling and referrals. For greater clarity on the scope of such APPs who can provide such services in Title X projects, the Department defines APPs to include those medical professionals who receive at least a graduate level degree in the relevant medical field and maintain a federal or State-level certification and licensure to diagnose, treat, and counsel patients. The term APP includes physician assistants and advanced practice registered nurses (APRN) who are performing increasingly critical roles within the health care system.[40] Examples of APRNs that qualify as an APP include Certified Nurse Practitioner (CNP), Clinical Nurse Specialist (CNS), Certified Registered Nurse Anesthetist (CRNA), and Certified Nurse-Midwife (CNM).[41] These APPs are qualified, due to their advanced education, licensing, and certification to diagnose and treat patients while advancing medical education and clinical research.[42] The final rule establishes this definition for purposes of Title X in § 59.2.

2. Definition of Family Planning

Summary of changes: The 2000 regulations do not define ''family planning.'' The proposed rule, at § 59.2, proposed to define ''family planning'' as ''the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved.'' Further, the proposed definition included ''a broad range of acceptable and effective choices, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility (including adoption).'' Family planning services are described in the proposed definition to include ''preconception counseling, education, and general reproductive and fertility health care to improve maternal and infant outcomes, and the health of women, men, and adolescents who seek family planning services, and the prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children).'' Family planning and family planning services are to be voluntary and never coercive. The proposed rule emphasizes that family planning ''does not include postconception care (including obstetric or prenatal care) or abortion as a method of family planning. Family planning, as supported under this subpart, should reduce the incidence of abortion.'' The proposed rule indicates that prenatal referrals are required and medically necessary for the health of the pregnant mother, as well as the unborn baby, and are not included in this prohibition.

The Department finalizes this definition with changes, including clarifying the role of adoption as a family planning activity by permitting Title X providers to provide information about or referrals for adoption as a Title X service; increasing the understanding that family planning must not be coercive and must always be voluntary; and by making technical edits for consistency and readability.

Comments: Some commenters state there is little support for the Department to define family planning. They note that, while the Department says the definition's purpose is to avoid the ''risk of the intentional or unintentional use of Title X funds for impermissible purposes,'' the Department cites no actual violation of Title X requirements in relation to the provision of abortion services.

Some commenters oppose the explicit exclusion of abortion in the definition. One commenter notes that abortion does impact the number and spacing of children and should not be excluded from the meaning of family planning. Such commenters state that couples use abortion as a method of family planning to determine their desired number of children or to space them. They contend that excluding abortion from the definition by labeling it postconception care reflects a failure to consider who may want or need to have an abortion. Additionally, one commenter states that the last sentence of the new definition should be stricken because reducing abortion was not the intent of the enabling legislation. Some commenters suggest the definition creates ambiguity concerning abortion that is not used as a method for family planning.

Many commenters ask the Department to eliminate language that mentions natural family planning and fertility awareness-based methods (FABMs), contending that the definition prioritizes those methods over other contraceptive methods. Such commenters worry that the definition de-emphasizes contraception in favor of abstinence, natural family planning, and fertility awareness-based methods that the agency has long recognized are less-effective methods of family planning. Commenters also contend, for example, that fertility awareness-based methods do not fit everyone's lifestyle and are ineffective for many women; that abstinence programs are ineffective and ignore the needs of participants already engaged in sexual activity; that avoiding sex as a family planning method conflicts with CDC, WHO, and UN definitions of family planning; and directing Title X funds towards natural family planning is unnecessary as 93% of sites report offering it and less than 0.5% of female Title X contraceptive users rely on it.

Some commenters ask, in the alternative, that if the Department does not eliminate language that mentions natural family planning, the Department instead clarify whether it intends to prioritize and promote natural family planning and other FABMs for Title X patients over other contraceptive options, and if so, to provide its justification, and explain why that would not undermine patients' ability to obtain voluntary care free from coercion. Some commenters also state that the proposed language may ''blur the lines'' between choices, methods,

[40] Other Federal Agencies refer to APPs as Mid-Level Practitioners. *See* U.S. Department of Justice Drug Enforcement Diversion Control Division, *Mid-Level Practitioners Authorization by State,* Drug Enforcement Administration, *https://www.deadiversion.usdoj.gov/drugreg/practioners/index.html.* ''Mid-Level Practitioners'' and ''Advanced Practice Provider'' generally describe the same group of individuals; the Department here chooses the latter term in recognition of the increasingly critical and advanced roles that PAs and APRNs play within the clinic environment.

[41] The Department recognizes the wide range of specializations within the nursing profession. These examples were selected as APPs due to their advanced medical degrees, licensing, and certification requirements. *See* National Council of State Boards of Nursing, *APRNS in the U.S, https://www.ncsbn.org/aprn.htm. See also* American Association of Nurse Practitioners, *What's a Nurse Practitioner (NP)?, https://www.aanp.org/about/all-about-nps/whats-a-nurse-practitioner* (stating that ''[a]ll NPs must complete a master's or doctoral program and have advanced clinical training beyond their initial professional registered nurse preparation'' while being regulated by the licensing requirements of each State where the individual practices).

[42] *See,* Catherine S. Bishop, *Advanced Practitioners Are Not Mid-Level Providers,* J Adv Pract Oncol, (Sept. 1, 2012), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4093350/* (noting that Physician Assistants and Advanced Practice Nurses ''have at least a master's degree and many hold doctorates.'') *See also* Jacquelyn Corley, *Advanced-Practice Providers Are Key to America's healthcare Future,* Forbes, (Mar. 16, 2017), *https://www.forbes.com/sites/realspin/2017/03/16/advanced-practice-providers-are-key-to-americas-healthcare-future/#3d25c1f95998.*

and services, and contend this may diminish the range of each provided under the Title X program.

One commenter says the definition of family planning should ensure that women have sufficient access to evidence-based family planning and sexual health information, and the full range of medically accepted forms of contraception, in order to avoid issues that may arise in light of the new definition of family planning. Commenters express concern that the definition would leave many women without access to contraception or the most effective methods to prevent pregnancy. Other commenters oppose the definition of family planning because they contend negative impacts will result, such as driving some providers out of business; increasing the incidence of unintended pregnancy; increasing the incidence of sexually transmitted diseases; leading to grantees offering a more limited scope of services, making it difficult for patients to receive care they need; and leading to increased costs on the health care system as the result of unintended pregnancies.

One commenter supports including only preconception services in the definition of family planning, and states that the definition empowers the Department and Title X providers to provide comprehensive services. Another commenter similarly states that, by placing postconception care beyond the scope of Title X, and by expressly excluding abortion from the definition of family planning, the definition reorients Title X towards its intended purpose.

Other commenters oppose including only preconception services in the definition. One commenter contends that excluding postconception care disrupts the continuity of care for family planning clients. The commenter additionally states the limitation is contrary to national standards that promote early access to prenatal care. Another commenter argues that the government is discriminating against women who seek abortions by defining the practice as postconception care and excluding this type of care from the definition of family planning, but then requiring projects to refer all pregnant woman for prenatal care.

Some commenters request that the Department eliminate language referring to adoption. Commenters assert that the management of infertility, including adoption, exceeds the intent of the program as its inclusion is beyond the language of the Title X statute. Including adoption would put a strain on the program, commenters contend, as it would redirect a large amount of Title X funds. Additionally, commenters contend adoption is a postconception activity, and say its inclusion in the definition contradicts the definition's statement that family planning only includes preconception activities.

Some commenters also argue that excluding abortion is a violation of the First Amendment's religion clauses due to preferring some religious ideas over others and enforcing religion with the power of the government. They contend excluding abortion, and in their view emphasizing natural family planning, is characteristic of particular religious views.

Finally, one commenter states that the rule does not make it clear whether female or male sterilization services are considered within the scope of family planning methods, and contends they are consistent with the goal of determining the number and spacing of one's children.

Response: Title X of the Public Health Service Act confers broad authority on the Secretary of Health and Human Services ''to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).'' 42 U.S.C. 300(a). Congress placed specific limitations on what constitutes appropriate ''family planning'' for purposes of Title X. In Section 1008, Congress expressly required that ''[n]one of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.'' 42 U.S.C. 300a–6. Congress did not fully define ''family planning'' in the Title X statute. However, section 1006 authorizes the Secretary to promulgate regulations governing grants and contracts in the program. 42 U.S.C. 300(a). Accordingly, the Department has statutory authority to define ''family planning'' for the purposes of the Title X program.

Given the statutory emphasis on family planning, the Department believes defining the phrase is important to ensure a coherent and reliable implementation of Title X, consistent with carefully considered statutory parameters. The Department disagrees with commenters who contend there is little support for creating the definition for family planning because no violations have been identified. The Department does not have to identify violations in order to interpret a statutory term. The Department deems it useful to develop and maintain a definition of family planning, in order to establish the scope of the Title X family planning program, to ensure consistency across the program, and to meaningfully ensure that the family planning projects implemented under Title X grants and/or contracts provide a broad range of family planning methods and services, consistent with the Title X statute. The Department believes it is appropriate to exercise its rulemaking authority to define family planning as a term important to the scope of the Title X projects, the development of grant applications, and the issuance of grants and contracts in the Title X program.

Moreover, the Department notes that the definition will address in part its concern that the requirement for abortion referrals, as provided in the 2000 regulations, violates or leads to violations of section 1008's prohibition on funding Title X projects where abortion is a method of family planning. Concerns about family planning methods being used indirectly to violate requirements of the program dates back at least to the 1988 regulations. There, the Department stated, in § 59.14, that a ''Title X project may not use prenatal, social service or, emergency medical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning . . .'' 53 FR at 2945. This provision was upheld by the Supreme Court.[43] That the 2000 regulations required certain abortion referrals, in a way the Department, both previously and now, deems inconsistent with the Title X statute, is itself a cause of confusion about what should and should not be included as ''family planning'' under the Title X program, and justifies the Department's decision to establish a definition of family planning in this rule.

The Department disagrees with the many commenters that oppose defining ''family planning'' to exclude abortion and that urge the Department to define the term to include abortion. Such commenters appear to be either unaware of, or confused about (or to have intentionally ignored), the fact that Title X explicitly excludes[44] funding for projects where abortion is a method of family planning. The Department is statutorily required to exclude abortion as a method of family planning for purposes of the Title X program, *see* 42 U.S.C. 300a–6, and has no statutory authority to consider family planning under Title X to include abortion. The

[43] *Rust* v. *Sullivan,* 500 U.S. at 192–195.

[44] *See* 42 U.S.C. 300a–6.

fact that so many commenters are unaware of or confused about this requirement, and ask the Department to include abortion as a method of family planning in violation of the Title X statute, reinforces the Department's view that it is appropriate to define ''family planning'' to clarify the scope of the Title X family planning program, as well as to establish other requirements that separate the Title X family planning program and Title X family planning projects from abortion as a method of family planning.

Some commenters ask how the definition applies to abortions that are not used as a method of family planning. Section 1008 prohibits funding Title X projects where abortion is a method of family planning, but does not preclude referral for services to address health issues or conditions where treatment constitutes a medical necessity. In addition, annual Title X appropriations law has consistently barred the expenditure of Title X funds for abortion. *See* HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. 2981, 3070 (funds provided to Title X projects ''shall not be expended for abortion''); Consolidated Appropriations Act 2018, Public Law 115–141, Div. H, Title II, 132 Stat. 348, 716 (same); Consolidated Appropriations Act 2017, Public Law 115–31, Div. H, Title II, 131 Stat. 135, 521 (same); Consolidated Appropriations Act 2016, Public Law 114–113, Div. H, Title II, 129 Stat. 2242, 2602 (same). Title X primarily focuses on the provision of certain preconception health care services. Nevertheless, because of certain specific statutory provisions, the Department believes that Title X providers can provide certain counseling and referrals in a postconception setting, if compliance with the Title X statutory and regulatory restrictions concerning abortion is maintained. The Department has interpreted Title X to allow nondirective postconception pregnancy counseling because of an express annual appropriations rider on nondirective pregnancy counseling may be offered. In addition, under the Infant Adoption Awareness grants program, Congress specified that eligible health centers (which includes Title X clinics) should receive training on providing adoption information and referrals, and that the Secretary should encourage the same,[45] therefore expressing its intent that postconception adoption information and referrals be included as part of any nondirective counseling in Title X projects. Thus, adoption counseling and referral is appropriate under Title X, since Congress specified that Title X clinics and providers were eligible health centers to whom adoption related training should be offered.[46] However, this provision differs from the actual provision of adoption services to an interested family, which is outside of Title X health care services. In addition, Title X funds may not be spent on childbirth services or prenatal care, but referrals for prenatal care can be required because it is medically necessary for pregnancy and provides information rather than services.

Taking those provisions, the annual appropriations provision, and section 1008 together, the Department has concluded that Title X projects may allow a physician or APP to provide nondirective counseling on abortion generally as a part of nondirective pregnancy counseling, and may refer for abortion for documented emergency care reasons, but may not refer for abortion as a method of family planning. Similarly, the nondirective pregnancy counseling can include counseling on adoption, and corresponding referrals to adoption agencies. As a consequence, the Department considers it appropriate to define ''family planning'' as (1) excluding abortion, (2) permitting the provision of nondirective pregnancy counseling (including abortion and adoption), and (3) including and requiring Title X projects to refer for prenatal care services.

The Department disagrees with commenters who oppose the last sentence of the definition because, in the commenters' view, Congress's intent in Title X did not include the reduction of abortion.[47] The 1988 regulations, which were upheld by the Supreme Court in *Rust,* contained the same statement, that ''[f]amily planning, as supported under this subpart, should reduce the incidence of abortion.'' *See Rust,* 500 U.S. at 193. The Court stated, ''Here the Government is exercising the authority it possesses under *Maher* and *Harris* v. *McRae,* 448 U.S. 297 (1980), to subsidize family planning services which will lead to conception and childbirth, and declining to 'promote or encourage abortion.' The Government can, without violating the Constitution, selectively fund a program to encourage certain activities it believes to be in the public interest, without at the same time funding an alternative program which seeks to deal with the problem in another way.'' *Id.* In choosing to fund family planning methods, but declaring no Title X project can receive funding where abortion is a method of family planning, Congress decided to encourage certain activities as an alternative to funding abortion. The Court explained such a decision neither infringes upon nor does it constitute State interference in abortion; it represents a legitimate choice by the government to encourage some activities over others. *Id.* Reducing abortion is also commonly identified by the government, researchers, private organizations, and many public commenters here, as being a potential and significant benefit of family planning.[48] The Department, therefore, concludes it is appropriate to define one purpose of family planning, under the Title X family planning program, as being to reduce the incidence of abortion.

Defining family planning, for the purposes of Title X, to exclude abortion, and as being, at least in part, for the purpose of reducing abortion, does not suggest that Title X projects may engage in directive pregnancy counseling to reduce abortion. As discussed below, when a Title X physician or an APP engages in pregnancy counseling, such counseling must be nondirective. But the fact that reducing abortion is not a goal of pregnancy counseling under Title X does not mean that the Department's provision and promotion of family planning in all other contexts cannot be undertaken, in part, for the purpose of reducing the incidence of abortion. When the Department funds Title X projects that provide a broad range of family planning methods and services to prevent pregnancy, the results will likely include, among other things, a decrease in pregnancy and with it, a decrease in the incidence of abortion as a method of family planning.

The Department disagrees with commenters who oppose the

[45] *See* 42 U.S.C. 254c–6 (Congress authorized the Department to make grants ''for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.'').

[46] Finalizing the definition of family planning to include adoption information and referrals is also part of the Department's fulfillment of its duties under section 330F, should grants under that section be funded.

[47] The final sentence of the proposed definition of ''family planning'' is that ''[f]amily planning, as supported under this subpart, should reduce the incidence of abortion.''

[48] *See, e.g.,* Guttmacher Institute, *New Clarity for the U.S. Abortion Debate: A Steep Drop in Unintended Pregnancy Is Driving Recent Abortion Declines,* (March 18, 2016), *https://www.guttmacher.org/gpr/2016/03/new-clarity-us-abortion-debate-steep-drop-unintended-pregnancy-driving-recent-abortion* (stating that ''expanding women's access to family planning services not only protects U.S. women's health and rights, it also reduces abortion rates.'')

definition's references to natural family planning, fertility awareness-based methods, and choosing not to have sex (which some commenters refer to as abstinence), or who say the definition emphasizes those methods over contraception or other methods. The definition of ''family planning'' does not emphasize or prioritize those methods over contraception, but mentions them alongside contraception and other family planning methods in a non-exhaustive list of methods of family planning. To the extent many commenters oppose including natural family planning and fertility awareness-based methods in ''family planning'' at all, the commenters are arguing against the Title X statute, not this rule. Title X specifies that the Department fund projects ''which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods . . .).'' 42 U.S.C. 300(a). Congress has, thus, dictated that, for the purposes of Title X, family planning includes natural family planning methods. As a consequence, the Department lacks the authority to exclude natural family planning—or any other family planning method or service mentioned in the Title X statute—from the definition of family planning in Title X. Since Congress explicitly mentions it in Title X as part of family planning services to be provided by a Title X project, the Department declines to delete or deemphasize natural family planning.

The term ''fertility awareness-based methods'' is a more recent term that refers to the same general kind of family planning methods that Congress intended when it included ''natural family planning'' in the Title X family planning program. The science of natural family planning methods, and other family planning methods (including contraceptives), has advanced significantly since Congress enacted Title X in 1970. As explained further below, the term ''fertility awareness-based methods'' includes similar family planning methods and services captured by the term ''natural family planning'' in the statute. But for greater clarity as to the scope of the program, the Department finalizes the definition as proposed to mention fertility awareness-based methods alongside natural family planning.

The Department agrees with commenters who support Congress's inclusion of natural family planning methods in Title X. Some commenters point out that very few women use natural family planning methods within Title X, but there is insufficient information on why this may be the case. It may be that the method is not presented by a clinic as a meaningful option or it may be that staff are not adequately trained in the method. In general, an increasing number of persons are choosing natural family planning methods,[49] at the same time that the scientific basis and approvals for fertility awareness-based methods are also increasing.[50] Requiring projects to provide natural family planning, in addition to contraceptives and other family planning methods and services, does not mandate that such projects provide them in the same quantity, but that natural family planning be meaningfully included in the project.

In response to this and other sections of the proposed rule, some commenters contend natural family planning or fertility awareness-based methods should be excluded from Title X projects because they are not effective. The Department does not find the exclusion of such methods to be consistent with the direction of Congress in section 1001(a), which explicitly includes natural family planning in the range of family planning methods provided through Title X. The commenters also provide no evidence to conclude that natural family planning is categorically ineffective, even if such a conclusion could overcome the statutory language including natural family planning as among the methods of family planning that may be offered in a Title X project. These commenters do not acknowledge that, in the last 40 years, the science behind, and efficacy of, fertility awareness-based methods has improved significantly, leading to FDA approval of certain medical products involving such methods and to increased utilization of these methods.[51] The Department also does not find it consistent with the principle of patient choice categorically to deprive individuals or families of the option of obtaining natural family planning or fertility awareness-based family planning methods within Title X projects.

The Department similarly disagrees with commenters who oppose including choosing not to have sex as a method of family planning. Choosing not to have sex, either for a long period of time or for selected intervals, or choosing not to have sex as often or with as many sexual partners, is clearly a preconception method of family planning for reducing unintended pregnancy. In addition, choosing not to have sex or engaging in sex with a single monogamous partner is protective of preconception health, particularly because it protects an individual from exposure to STDs that may contribute to infertility and negative health outcomes. As a viable method for delaying or avoiding pregnancy altogether, the Department would be remiss if it were to exclude this method, since consistently choosing not to have sex is the most effective way to prevent pregnancy. As with natural family planning, the inclusion of this method within the definition of ''family planning'' does not invalidate other methods within that definition, nor mean that every Title X clinic has to provide counseling services related to this method of family planning.

The Department therefore disagrees with commenters who contend that recognizing these options within the definition of family planning will diminish an individual's ability to choose another form of family planning. Projects must also provide contraception, and can do so in proportion to the demand for such methods. The individual's free and informed choice to select a family planning method is respected by requiring projects to provide the broad range of family planning options that Congress contemplated in the statute, and to allow individuals to freely select the method they prefer. The definition of family planning merely specifies that these methods are included in the broad range of family planning methods available within each Title X project. Projects may comply with the statutory directive when they include natural family planning in the broad range of family planning methods and services that must be provided. The definition also specifies that family planning is never to be coercive and must always be strictly voluntary. This precludes the conclusion, put forth by some commenters, that including natural family planning or choosing not to have

[49] The Guttmacher Institute reported that the percentage of women using natural family planning doubled between 2008 and 2014. Megan L. Kavanaugh and Jenna Jerman, *Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,* Guttmacher Institute, 97 *Contraception* 1:14–21 (Jan. 2018), *https://www.contraceptionjournal.org/article/S0010-7824(17)30478–X/fulltext.*

[50] *See e.g.,* FDA News Release, *FDA allows marketing of first direct-to-consumer app for contraceptive use to prevent pregnancy,* (Aug. 10, 2018), *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm616511.htm (permitting marketing of a fertility-awareness-based mobile medical application).*

[51] *See, e.g.,* Shawn Malarcher, et. al., *Fertility Awareness Methods: Distinctive Modern Contraceptives,* 4 Global Health: Science and Practice 13, 13 (2016), *available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4807745/pdf/013.pdf* (stating fertility awareness methods of contraception have been tested and proven effective at pregnancy prevention and safe to use).

sex in the definition imposes a requirement on any clients.

The Department also notes that this final rule is consistent with the proposed rule, which explicitly includes contraception in the definition of family planning. Contrary to the suggestion of some commenters, the definition does not place a lower priority on contraception as a method of family planning, nor somehow invite Title X providers to pressure clients to use natural family planning instead of contraception. The rule, both as proposed and finalized, will allow funded projects to provide all acceptable and effective Title X family planning methods, while ensuring that participating entities or service sites that wish to offer only a single method or a limited number of methods may also participate in Title X projects, so long as each Title X project, as a whole, provides a broad range of family planning methods and services, including contraception and natural family planning.

Clarifying that those options fall within the program is well within the purview of the Title X program, and ensures individuals' voluntary and informed access to the family planning option of their choice. The Department does not agree that the definition blurs lines between different family planning options, methods, or choices. Rather, the Department agrees with comments suggesting that the new definition of family planning will expand access to a broad range of family planning methods and services and will ensure patients have the ability to make voluntary and informed family planning choices. To provide clarity and ensure that duplicative terms are not interpreted with different meanings, the Department revises the definition by using the words used in the Title X statute, ''methods and services,'' instead of the word ''choices'' that was used in the proposed rule. The Department further modifies the sentence ''Family planning and family planning services are never coercive and are strictly voluntary'' to read ''Family planning methods and services are never to be coercive and must always be strictly voluntary.'' This clarifies the terms in the sentence and also further aligns the definition with the voluntary requirements set forth in sections 1001 and 1007 of Title X.

The Department acknowledges the concerns of commenters who contend the proposed definition would leave women without access to contraception or other methods of family planning, but believes that these concerns are overstated. The Department is aware of reported success rates regarding various forms of preconception family planning for those engaged in sexual activity. The Department wishes to emphasize that, consistent with the statutory provisions, contraception will continue to be a significant category of family planning methods for Title X projects. This is why the family planning definition specifically mentions contraception among other family planning methods and services and why § 59.5 continues to require a broad range of acceptable and effective family planning methods and services within Title X projects. The Department does not intend to implement or enforce these regulations to have any limiting effect on Title X organizations that offer contraception options if those organizations are otherwise compliant with the Title X grant requirements. The Department believes that the proposed rule broadens access for women seeking preconception family planning options by permitting grantees or subrecipients to provide various or specialized forms of family planning, while also ensuring that projects, as a whole, provide a broad range of family planning methods and services.

The Department finds there is insufficient evidence to support the contention of some commenters that negative impacts will result from the definition, such as driving out some providers, increasing unintended pregnancy, or increasing STDs. The definition encompasses contraception and other methods that these commenters support, and it will not deprive Title X projects of the ability to offer any such methods or services. To the extent commenters believe these negative results will occur because the definition of family planning excludes abortion, and includes natural family planning, both parameters have been mandated by the Title X statute for decades. Any such effect, then, would be attributable to implementing the program as Congress directed.

The Department disagrees with commenters who ask that the definition specify that all family planning methods and services must be ''medically approved.'' The Department also discusses this issue below concerning the change in such language at § 59.5. When Congress specified what family planning methods and services Title X projects must provide, Congress directed that the methods and services be ''acceptable and effective''; it did not specify that they be ''medically approved.'' The Department also does not understand, and commenters fail to explain, what the addition of ''medically approved'' to the definition would mean in practice. Family planning methods and services are often provided through licensed health care professionals. Thus, it is true of all family planning methods or services provided by Title X providers that at least one medical professional or clinic has ''approved'' the method or service, by virtue of providing it to the client. It is not clear what else a requirement of medical approval might mean, or what commenters believe it to mean, if inserted into the family planning definition. For example, would approval by one medical doctor suffice, or would some larger number need to approve, and if so, how many; would certain medical organizations, or governmental organizations, or both, need to approve, and if so, which ones; would a certain level of medical consensus need to exist concerning a particular method or service, and if so, how would the Department measure that consensus; and when doctors and medical organizations disagree either about a family planning method or service, how would that requirement apply? For all of these reasons, the Department does not believe the Title X statute requires the term ''medically approved'' be included in this definition, and does not believe including it is appropriate. The Department instead relies on the statutory language ''acceptable and effective'' as sufficiently ensuring that family planning methods and services are appropriate for clients served in Title X projects.

The Department disagrees with commenters who contend the definition of family planning violates the religion clauses of the First Amendment. As discussed in *Rust,* the Supreme Court has stated many times that the Constitution does not require the government to fund abortion, and it allows the government to encourage alternatives to abortion. *See Rust,* 500 U.S. at 201. The inclusion of natural family planning in the definition of ''family planning'' is a congressional mandate and has existed for decades—there is no legitimate legal reason to believe it violates the First Amendment.

In response to commenters asking whether family planning includes sterilization, the Department clarifies that acceptable and effective methods of sterilization are a preconception means of implementing an individual's or family's decision as to the number and spacing of births.

The Department agrees with commenters that support the limitation in the proposed definition that family planning does not include postconception health care (as distinct from certain types of postconception counseling/information, such as in the

case of congressionally permitted nondirective pregnancy counseling), but does include preconception counseling, education, and health care that can improve maternal and infant outcomes; the health of women, men, and adolescents who seek family planning services; and the prevention, diagnosis, and treatment of infections and diseases that may threaten childbearing capability or the health of the individual, sexual partners, and potential future children. This is consistent with the legislative history of the Title X program, which emphasizes Congress's intent for the program to focus on preconception health services as important to family planning.[52] This Congressional intent is another basis for excluding abortion as a method of family planning from the definition of family planning for the purposes of Title X, because abortion is a postconception service. As discussed further below, Title X projects are not required to provide abortion information or counseling, and if nondirective pregnancy counseling is offered, any abortion counseling also must be nondirective.

The Department finds that a distinction between preconception health care services and postconception services is effective and can be more cost-effective. The Department disagrees with commenters who contend limiting family planning to preconception care is contrary to national standards. For the purposes of the Title X program, the limitation to preconception care is appropriate and consistent with Congressional intent. Any concern with national standards is met and addressed by encouraging Title X projects to offer either comprehensive primary health care services onsite or have a robust referral linkage with primary health care providers who are in close proximity to the Title X site. The Department will administer Title X funds to focus on permissible preventive care and preconception family planning, while promoting robust referral networks to ensure that clients have ready access to non-Title X health care services that they need, including treatment for health conditions that are not provided by Title X and for postconception care (other than abortion as a method of family planning).

The Department appreciates and responds to comments raising concern about the inclusion of adoption in family planning services and clarifies the purpose of the rule in this regard, finalizing a change to the language concerning adoption. Adoption is a method by which families can plan their family size, to either increase it, decrease it, relieve burdens attendant to insufficiently spaced children, or deal with infertility (although infertility management is not the only way in which adoption is a method of family planning, and adoption is not the only method of infertility management). Insofar as adoption is considered a preconception method by which families may plan their family size or respond to infertility, it fits comfortably within the broad range of family methods and services contemplated by Title X. Although many commenters focus on the important role of Title X providers in preventing unintended pregnancy through contraception or not having sex, Congress clearly intended Title X to support family planning through more than preventive services, as evidenced by the emphasis on infertility services in Title X. *See* 42 U.S.C. 300(a) (Title X family planning projects required to ''offer a broad range of acceptable and effective family planning methods and services (including natural family planning, infertility services, and services for adolescents)'').[53] The Department thus found and continues to find that Title X is an important resource for individuals seeking assistance to have children, and adoption is one method by which a Title X client who is not pregnant may seek to have children.[54]

Moreover, Congress has expressed its intent that postconception adoption information and referrals be included as part of any nondirective counseling in Title X projects when it passed the Children's Health Act of 2000, adding section 330F (''Grants Regarding Infant Adoption Awareness'') to the Public Health Service Act on October 17, 2000. Public Law 106–310, 114 Stat. 1101, sec. 1201, codified at 42 U.S.C. 254c–6 (hereinafter ''Infant Adoption Awareness grants''). There, Congress authorized the Department to make grants ''for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.'' 42 U.S.C. 254c–6(a)(1). Congress specified that grantees shall offer that training to Title X grantees and the Secretary shall make reasonable efforts to encourage Title X grantees to participate in that training.[55] At least some major organizations ''understood the legislation and the guidelines for the Program to strongly suggest that those working in clinics receiving funds through Title X family planning grants . . . be the principal target for the training.'' [56] If the provision to pregnant women, of nondirective adoption counseling and referral were not appropriate under Title X, Congress would not have specified that Title X clinics and providers were eligible health centers to whom such adoption related training should be offered. This interpretation has been carried into current practice by major adoption organizations, such as The National Council for Adoption.[57]

By contrast, because of Congress's primary focus on funding preconception care in Title X, the Department deems the provision of adoption services themselves to be outside the scope of the Title X program. This clarification should address the concern by some commenters about a potential strain on resources of the Title X program caused by the inclusion of adoption in the family planning definition. Title X providers may provide adoption counseling, information, and referral as a voluntary family planning service for non-pregnant clients as a means of addressing health care issues related to

[52] *See* H.R. Rep. No 91–1667, at 8–9 (1970) (Conf. Rep.) (emphasizing the intent of Congress that Title X funds specifically support preconception family planning, stating ''[i]t is, and has been, the intent of both Houses that funds authorized under this legislation be used only to support preventive family planning services, population research, infertility services and other related medical, information, and educational activities. The conferees have adopted the language contained in section 1008, which prohibits the use of such funds for abortion, in order to make clear this intent.'').

[53] *See* 53 FR at 2922 (the Department historically found ''it is clear that Congress intended the term ''family planning'' to be broader in scope than simply contraception, as infertility services are included as one of the mandatory services listed in section 1001(a) of the Act.'').

[54] *Id.* This interpretation is consistent with the Department's history of enforcing Title X regulations regarding adoption: ''Both approaches [adoption and infertility services] constitute legitimate means of determining family size and spacing, but adoption is simply one means of addressing the broader problem of infertility.'' *Id.*

[55] *See* 42 U.S.C. 254c–6(a)(5) & (6)(A) (adoption organization required to make reasonable efforts to ensure that training is provided to, among others, ''eligible health centers that receive grants under section 1001 (relating to voluntary family planning)''; with respect to eligible health centers that received grants under section 330 or 1001, ''[t]he Secretary shall make reasonable efforts to encourage eligible health centers to arrange for designated staff to participate in such training. Such efforts shall affirm Federal requirements, if any, that the eligible health center provide nondirective counseling to pregnant women.'').

[56] *See* The National Council For Adoption, *NCFA's Infant Adoption Awareness Training Program—A Successful Model,* 193.

[57] Finalizing the definition of family planning to include adoption information and referrals is also part of the Department's fulfillment of its duties under section 330F, should grants under that section be funded.

fertility and reproduction, such as infertility, and as part of nondirective postconception counseling, but may not provide adoption services themselves within the project.

This approach is consistent with the Title X parameters and with the Department's history of implementing Title X. In the 1981 Title X program guidelines, ''Program Guidelines for Project Grants for Family Planning Services,'' the Department allowed nondirective counseling on, and referral for, adoption and foster care when a woman with an unintended pregnancy requested information on her options. The 1988 regulations continued this support for encouragement of counseling on and referral for adoption. The 2000 regulations required both counseling and referral on adoption, if the client requested such assistance. Given this history and Congress's expressed intent, the Department concludes that Title X funds may facilitate access to adoption through nondirective adoption counseling and referral as a part of the nondirective counseling offered to pregnant clients.

Congress's express intent to include adoption information and referral in Title X projects can be contrasted with its express intent to exclude Title X funding from any projects where abortion is a method of family planning. The Title X statute contains no similar prohibition on funding projects where adoption is a method of family planning, and section 330F requires the Secretary to encourage the inclusion of adoption information and referrals in the Title X program. Similarly, the Title X statute contains no similar prohibition on funding projects that include postconception referrals for prenatal care, which is necessary for pregnancy as a medical condition. Thus, the Department disagrees with commenters contending that the definition improperly discriminates by treating adoption more favorably than abortion. Simply put, abortion is prohibited as a method of family planning within a Title X project and adoption is not. Given Congress's explicit differential treatment of adoption and abortion throughout the applicable statutes, the definition is an appropriate exercise of the Department's authority to promulgate regulations to implement the Title X family planning program.

For all these reasons, the definition of family planning appropriately includes adoption information and referral as a family planning method. To clarify this, in response to questions from commenters about this issue, the Department modifies this aspect of the family planning definition in the final rule by changing ''the management of infertility (including adoption)'' to ''the management of infertility, including information about or referrals for adoption.''

3. Definition of Grantee

Summary of changes: The 2000 regulations did not define a ''grantee'' under Title X. The proposed rule, at § 59.2, proposed to define ''grantee'' as ''the entity that receives Federal financial assistance by means of a grant, and assumes legal and financial responsibility and accountability for the awarded funds, for the performance of the activities approved for funding and for reporting required information to the Office of Population Affairs.''

There were no substantive comments regarding this definition.

The Department finalizes the definition of ''grantee'' in § 59.2 without change, except for minor grammatical corrections.

4. Definition of Low Income Family

Summary of changes: The 2000 regulations at § 59.2 defined ''low income family'' by income and allowed the project director to determine ''good reasons'' where an individual may qualify even if income exceeded the defined amount. Pursuant to an example in the definition, minors who wish to receive services on a confidential basis are considered on the basis of their own resources. The proposed rule, at § 59.2, proposed to modify the existing definition of ''low income family'' relating to minors by requiring the program to document its efforts to encourage the unemancipated minor to involve his/her family in the decision to seek family planning services, in order to ensure compliance with the applicable Title X and appropriations law provisions on the issue. In addition, the proposed rule included a provision whereby the project director may consider a woman as a low income family when her employer-sponsored health insurance does not cover certain contraceptives because of her employer's religious or moral objection to such contraceptives. The Department recognizes that a woman's insurance coverage may relate to her ability to pay for family planning services. The Department finalizes the proposed modifications with no substantive changes to the definition with respect to unemancipated minors, but with some minor grammatical corrections. However, in response to public comments, the Department also finalizes paragraph (2) under the definition for low-income family for cases involving ''payment for contraceptive services only,'' where the woman's employer ''does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage.'' This final rule clarifies that, in these cases, the project director may exercise discretion under the existing ''good reason'' exception to ''consider her insurance coverage status as a good reason why she is unable to pay for contraceptive services.'' In making this determination, the project director ''must also consider other circumstances affecting her ability to pay.'' This final rule then provides mechanisms by which a director may determine whether the woman is from a ''low income family'' or is eligible for a discount for contraceptive services on the schedule of discounts provided for in § 59.5.''

Comments: Some commenters support the proposed changes to the definition of low income family. Some of these commenters support the encouragement of family participation in the family planning decisions of minors. Some also support the definition's clarification about how women may be eligible to receive contraceptive services where health insurance from their employers does not cover those services due to their employers' religious or moral objections. Some commenters support the change because they say it assists the Department in not requiring employers to violate their religious or moral beliefs, while protecting the ability of women to receive family planning services.

Commenters support the encouragement of family participation in the family planning decisions of minors, noting that it does not block access to family planning services. Rather, as comments explain, family participation should be the standard for any health care service provided to minors because they do not always know their family history and certain contraceptives are contraindicated for females with certain health conditions. In addition, parents are better able to direct health care decisions for their children if they are aware of other health care services and products that their children are receiving.

Some commenters oppose the definition's requirement that emancipated minors be charged based on their own income only if there is documentation of specific actions taken with respect to each minor to encourage such family participation. Such commenters are concerned this would threaten the confidentiality of these patients, as well as the patient-provider

relationship. Commenters state that providers typically use their expertise and judgment when deciding whether or not to encourage family involvement in the care of patients who are minors, and they identify situations in which family involvement should not be encouraged, such as in cases of neglect, coercion, or abuse. Some commenters are worried that the definition could cause strain on the patient-provider relationship and could lead to patients omitting information that would impact their care. Other commenters are concerned the definition would increase barriers for minors receiving low cost or free, confidential care. Such commenters conclude the revision runs counter to congressional intent, by including services for adolescents in the Title X statute, and exceeds the Department's authority under Title X. One commenter asks the Department to include additional language in the rule to ensure confidentiality for such minors; confidentiality of the information received about minors' circumstances; that the encouragement of family involvement is not coercive; and, that the minor's decision to involve his or her family is strictly voluntary.

Many commenters also oppose revising the definition of low income family to include women who are unable to obtain certain family planning services under their employer-sponsored health insurance policies due to their employer's sincerely held religious or moral objections. Many such commenters assert that Title X is already underfunded, and this revision would result in a large number of new Title X patients and could reduce services for actual low income patients, due to limited funds. Many stated that, if the Department does revise the definition, there must be increased Title X funding to account for the new patients.

Commenters who are health care providers note that the Department did not discuss the impacts this change would have on Title X patients and providers. Such commenters stated that the proposed rule did not provide evidence to support the conclusion that the Title X network can absorb the new patient population, nor address how the change would impact current patients. They also contend that the proposed rule did not discuss any financial impacts, operational impacts on projects, or corresponding costs. For example, commenters contend the Department did not explain how women are to show they are in an employer plan with a religious or moral objection to contraceptive coverage. Some Title X providers comment that requiring projects to verify that status would be cumbersome and involve administrative costs. Some commenters ask whether newly eligible patients would be able to obtain other services (*e.g.,* STD testing or Pap test) during a contraceptive visit and whether these services would also be free, and request guidance on that question.

Many commenters object to the new definition on the ground that previous interim final rules concerning contraceptives issued by the Department and the Departments of Labor and of the Treasury in October 2017 are not in effect based on court orders. Such commenters also contend the definition applies to women who are the policyholders of employer-sponsored insurance but not to other beneficiaries of such plans. Commenters further object that the definition does not guarantee coverage for such women but only states the project director may consider her as being from a low income family if good reasons exist under the definition. And commenters object that some women with insurance sponsored by an employer that objects to contraceptive coverage for religious or moral reasons might not have access to a Title X provider.

Some commenters assert that the Secretary does not have the legal authority to deem women as ''low income'' if their employer-sponsored plans have religious or moral objections to contraceptive coverage. Some commenters object that the definition only encompasses women, not men, whose employer-sponsored plans have religious or moral objections to contraceptive coverage, and they believe the definition does not encompass transgender men. One commenter contends the definition constitutes impermissible government subsidy of religious objections under the Establishment Clause of the First Amendment.

Response: The Department agrees with commenters generally supporting the revised definition concerning minors and women with employer-sponsored health insurance that does not cover contraceptive services based on the employer's religious or moral objections. Nevertheless, the Department has carefully considered all the comments, including comments opposing the changes, and is finalizing the definition with changes in response to those comments.

The Department disagrees with the suggestion of some commenters that its revised definition of low income family threatens the confidentiality of unemancipated minors. The revised definition explains that, if a project director seeks to consider only an unemancipated minor's own resources to determine whether the minor seeking confidential services qualifies as a low income family, the project director must document efforts to encourage family participation in the unemancipated minor's decision to seek family planning services. As discussed more fully below, such encouragement is specifically required by Congress and would occur within the context of the provider-patient relationship. Communications in that relationship are already confidential, and communications in which the provider encourages family participation in the minor's decision to seek family planning services would be subject to the same confidentiality requirements.

The Department similarly disagrees with the suggestion that this documentation requirement infringes on the judgment of medical professionals or threatens minors who are in abusive home circumstances. As discussed below, this final rule does not require a Title X provider to encourage family involvement ''if the Title X provider has documented in the medical record: (i) That it suspects the minor to be the victim of child abuse or incest; and (ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.'' Situations exist where confidentiality is important, and the Department incorporated those into the proposed rule. Moreover, the rule does not require family participation, but merely the encouragement of such participation. Inserting references to that general requirement in the definition of ''low income family'' concerning unemancipated minors simply reinforces the already existing statutory requirement—and ensures that Title X providers are actually complying with such requirements. To the extent that there were any infringement on the judgment of medical professionals, it would be the result of requirements imposed on the Title X program by Congress, requirements that the Department merely seeks to faithfully implement.[58]

Some commenters contend the Department lacks statutory authority to include as ''low income'' patients women who have employer-sponsored health insurance that does not cover contraceptive services based on the employer's religious or moral

[58] For additional responses to similar comments, please see the discussion of § 59.17, in which the Department responds more fully to similar objections.

objections, but this argument appears to be premised on a misunderstanding of the Department's proposal. Section 1006 gives the Secretary of HHS the authority to promulgate regulations governing grants and contracts issued under the Title X statute. 42 U.S.C. 300a–4. Section 1006 further specifies that projects receiving Title X grants or contracts must assure the Department that ''priority will be given in such project or program to the furnishing of such services to persons from low income families'' and that ''no charge will be made in such project or program for services provided to any person from a low income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.'' 42 U.S.C. 300a–4(c)(2). Section 1006 does not define ''low income family,'' but instead declares that the Secretary has discretion to define ''the term 'low income family'. . . in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs. . . .'' 42 U.S.C. 300a–4(c). Consequently, Congress granted the Secretary discretion to decide what constitutes a ''low income family'' for the purpose of giving priority of services to persons from such families, so as to ensure that economic status is not a deterrent to participating in Title X programs. *Id.*

For decades, the Department has implemented such regulations by defining ''low income family'' to mean a family whose total income does not exceed 100% of the Poverty Level guidelines,[59] along with individuals in families whose income does exceed that level but for whom the project director determines—based on unenumerated factors—that there are ''good reasons'' to conclude is ''unable'' to pay for family planning services. 42 CFR 59.2. The 2000 regulations provide the example of unemancipated minors who desire to receive services on a confidential basis. 42 CFR 59.2. The proposed addition to the definition maintains the same standard and simply specifies that one factor relevant to the ''good reasons'' standard is a woman's insurance status –which may affect her financial/economic status—with respect to the provision of contraception because of her employer's religious or moral objection to contraceptive coverage. Project directors already have this discretion under the 2000 regulations. The text of the proposed rule simply makes it explicit that a project director may rely on this factor in such circumstances. Some commenters are under the mistaken impression that the proposed rule requires project directors to consider women as being from a low income family if they have this insurance status, but the proposed rule said the project director ''may'' reach that conclusion, not that the director ''must'' do so.

This clarification does not, as some commenters contend, contradict the text or intent of the Title X statute. Congress authorized the Secretary to decide what constitutes a ''low income family'' in the program, and the Department's decades-old decision has allowed project directors to deem families ''low income'' even if their income exceeds 100% of the Poverty Guidelines. Thus, project directors might conclude based on a particular prospective client's insurance, income, and financial situation that the individual is unable to pay for family planning services. The proposed definition clarifies that a project director may—but is not required to—allow the same treatment for women with health insurance from an employer with a religious or moral objection to contraceptive coverage. And the definition instructs the project director to consider the woman's income in assessing her ability to pay. Thus, under the definition, if a project director concludes that a woman with that insurance status who has an income above 100% of the Poverty Guidelines[60] can afford to pay for family planning, the project director should conclude that she is not from a low income family. But the project director is also free to conclude, taking into account the particular circumstances, that a woman with that insurance status who has an income above 100% of the Poverty Guidelines cannot, in fact, afford to pay for family planning and should qualify as ''low income.'' That flexibility makes sense, as a woman's ability to obtain contraceptive services through an insurance plan may be relevant to her ability to pay for family planning services, and Congress has long directed that ''low income family'' be defined ''so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this title.'' 42 U.S.C. 300a–4(c).

Some commenters correctly read the proposed definition to mean the project director may, or may not, deem a particular woman who lacks insurance coverage for contraception because of her employer's religious or moral objection as being from a ''low income family,'' and they object to the Department giving the director that discretion. They seem to ask that the Department require the project director to deem such women as being from a ''low income family,''[61] regardless of her family's total annual income, or other factors contributing to her ability to pay for family planning.

The Department rejects that suggestion. It is true that the Department has required, in the ''low income family'' definition, that a project director ''must'' consider only an unemancipated minor's own resources if the minor seeks confidential services to determine whether the minor is from a ''low income family.'' In that way, the Department has previously exercised its regulatory authority to define ''low income family'' to include some persons who potentially have ability to pay for family planning—namely, minors from families who may have access to funds to pay for family planning services even if they are not employed. But in this case, the Department declines to finalize the definition to require project directors to consider a woman as being from a ''low income family'' based solely on her employer's religious or moral objection to contraceptive coverage. Some women in such circumstances may be unable to pay for family planning, but others may be able to pay. For example, some may be from families with total incomes well above the poverty level, and their other circumstances may reflect that they are able to pay. The Department wishes to leave this discretion with the project director.

The Department disagrees with commenters who contend the definition is confusing and leaves project directors with insufficient guidance. For decades, the definition of ''low income family'' has given project directors discretion to determine whether good reasons exist as to why a person cannot pay for family planning. The definition being finalized here provides more guidance, not less, for the project director's exercise of that discretion in the given scenario.

Some commenters object that projects will not be able to determine whether a woman's employer-sponsored insurance omits contraceptive coverage, or does so on the basis of religious or moral objections, but the Department believes

[59] *See* 42 U.S.C. 9902(2).

[60] The poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2). *See* Office of the Assistant Secretary for Planning and Evaluation, *U.S. Federal Poverty Guidelines Used to Determine Financial Eligibility for Certain Federal Programs* (Nov. 15, 2018, 9:51 a.m.), *https://aspe.hhs.gov/poverty-guidelines.*

[61] *See* 42 U.S.C. 300a–4.

this concern is overstated. This task is not fundamentally different from the task that projects face in determining what a person's income is, or whether, despite their income being above the poverty level, good reasons exist for considering them unable to pay for family planning. Guidance has set forth a variety of ways to seek information of this kind, including that set forth in the 2014 Title X program requirements.[62] Projects are also generally required to obtain third party payment or contribution for services that persons receive for free or at a sliding scale discount. All of these types of information are similar to the types of information that might demonstrate to a project that a woman has employer-sponsored health insurance that does not provide certain contraceptive coverage because the employer has a religious or moral objection to providing such coverage. A pay stub may demonstrate where a person works. Proof of insurance may demonstrate the person has coverage. A plan's summary of benefits and coverage would also indicate whether the plan covers the contraceptive services a woman seeks. And just as projects contact third party payers to obtain payment or contributions, projects could contact a woman's insurer to inquire whether the plan covers the particular contraceptive services and could ask if the lack of coverage is due to a religious or moral objection on the part of the plan sponsor. Where a woman wants to obtain the coverage confidentially, the project may not be able to make such contact, but in those cases, the same difficulty would be presented under the definition from the 2000 regulations, with respect to whether to deem those persons as having good reasons for their inability to pay for family planning services. The revised definition does not add uncertainty that is not already inherent in the good reasons discretion afforded to project directors. Rather, it adds clarity concerning one good reason that can form the basis of that good reason determination.

The Department understands the objection that project directors may seek more specific instructions on how to implement the definition, and also understands the concerns of some commenters who believe that women should automatically be deemed as being from a ''low income family'' if her employer-sponsored insurance coverage omits contraceptive services on the basis of a religious or moral objection. Such comments reflect that, for some women, not having contraceptive coverage may affect their ability to pay and, thus, their economic status. In light of this concern, and the desire to provide more specific direction sought by commenters, the Department is finalizing the definition with the modification that a project director may exercise discretion to consider such women as being from a ''low income family'' or eligible for a discount for contraceptive services on the schedule of discounts provided for in § 59.5, based on the impact that not having contraceptive coverage may have on their ability to pay for contraceptives.

Under the women's preventive services guidelines issued by the Department, certain plans (or issuers or plan administrators) are required to cover all FDA-approved contraceptives with no cost-sharing, unless an exemption applies to the plan based on sincerely held religious beliefs or moral convictions. *See* 45 CFR 147.132 (religious exemption criteria); 45 CFR 147.133 (moral exemption criteria); *see also* 45 CFR 147.131 (religious or moral accommodation criteria). In addition, various entities with religious or moral objections have obtained permanent injunctions from federal courts, entitling them to exemptions from the federal contraceptive coverage requirement.[63] Where a woman has health insurance coverage through an employer that does not provide the contraceptive services she seeks from a project, because her employer has a sincerely held religious or moral objection to providing such coverage, the project director may approximate the net effect on the woman's economic status by the average annual cost of the contraceptive services that would have been covered if her employer did not object. For example, if she seeks oral contraceptives, and her employer had covered oral contraceptives without cost-sharing, she would incur no out-of-pocket cost for oral contraceptives. If her employer omits oral contraceptives on the basis of a religious or moral objection, her annual cost as the result of that decision can be approximated by the annual out-of-pocket cost she would bear for oral contraceptives.

Consequently, in the final rule, the Department modifies the example involving a woman whose employer-sponsored health insurance does not cover contraceptives because of a religious or moral objection on the part of the employer. In such a situation, in determining whether such a woman's income is more than 100% of poverty level, or whether she is subject to sliding scale discounts for contraceptive services under § 59.5, the project director may reduce the woman's annual income by the annual out-of-pocket cost she would pay for the desired contraceptive services. The project director may estimate the annual cost based on the project director's expertise regarding the costs of contraceptive services, or reduce the woman's estimated total income by an estimated[64] average of $600 per year. This gives the project director additional discretion and guidance in considering the income status of a woman whose employer omits contraceptives from her insurance plan on the basis of a religious or moral objection.

The Department disagrees with commenters who assert that the example is discriminatory because it only refers to women. As discussed more fully below, the definition does not preclude men from seeking to establish good reasons for which they are unable to pay for family planning services. This specific example simply refers to women because it has mainly arisen in a context related to coverage for women's contraceptive services. A section of the PHS Act added by the Affordable Care Act,[65] specifies that certain group health plans and issuers shall provide coverage, with no cost sharing, of women's preventive services as provided by guidelines supported by the Health Resources and Services Administration (HRSA), a component of the Department. Section 2713(a)(4) does not apply to men and does not provide for cost-free coverage of men's contraceptive services. Where a woman's plan omits contraceptive coverage on the basis of religious or moral objections, it falls into an exemption to the guidelines set forth at 45 CFR 147.131 and 147.133. That exemption does not apply to men's contraceptive coverage, because the

[62] Office of Population Affairs, *Program Requirements for Title X Funded Family Planning Projects,* Health and Human Services, 12 (April 2014), *https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf* (''Although not required to do so, grantees that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients self-report.'').

[63] *See, e.g., Catholic Benefits Ass'n LCA* v. *Hargan,* No. 5:14–cv–00240–R (W.D. Okla. order filed Mar. 7, 2018), and *Dordt Coll.* v. *Burwell,* No. 5:13–cv–04100 (N.D. Iowa order filed June 12, 2018).

[64] *See* 83 FR 57536, 57551 (Nov. 15, 2018) (estimating the average annual cost of contraceptives at just under $600 per year).

[65] *See* 42 U.S.C. 300gg–13(a)(4) as added by the Affordable Care Act, Public Law 111–148, 124 Stat. 119, 131, sec. 1001 (adding new PHS Act section 2713).

underlying requirement of section 2713(a)(4) does not encompass preventive services for men. Given these circumstances, the Department deems it appropriate to illustrate how the project director could apply the discretion embodied in the existing low income family definition when a woman's employer-sponsored insurance plan omits contraceptive coverage on the basis of a religious or moral objection.

The Department notes that the definition maintains the decades-old discretion granted to the project director to deem a person as having good reasons why he or she cannot pay for family planning and therefore deem him or her as being from a ''low income family.'' Consequently, project directors may also consider a man's lack of access to insurance coverage for contraceptive services as potentially constituting a good reason why the project will consider the man as being from a low income family. The definition has required, and continues to require, project directors to take into consideration such indicia of ability to pay. This final rule mentions one specific context involving women who may not have access to contraceptive coverage as one possible application of the ''good reasons'' determination, but does not do so in an exclusive way, nor does it negate the applicability of the project director's pre-existing discretion to any person seeking services from the project.

Some commenters ask the Department to clarify whether a woman, who is considered as being from a low income family based in part on the lack of contraceptive coverage in her plan due to her employer's religious or moral objection, then qualifies to receive just the contraceptive services that her plan omits, or qualifies to receive all family planning services provided by the project, such as pap smears and STD testing. The Department clarifies that a project director may consider the woman with this insurance status as being from a low income family, or as qualifying for sliding scale discounts, for the purposes of her payment for the contraceptive services she seeks that are not covered by her insurance plan. The revision does not specify that such a woman will be deemed as being from a low income family for the purpose of receiving other services from the Title X project. Presumably, the woman would have insurance coverage for such other services, and the Title X provider could bill her health insurance company for them. Nevertheless, as noted above, the definition retains the decades-old discretion given to the project director to make a ''good reasons'' determination to deem a person as being from a ''low income family'' for the purposes of receiving all the services offered in the Title X project. The example specifies and clarifies how the project director's discretion could be applied in a particular situation, but it does not add limitations to the project director's discretion in other hypothetical cases raised by commenters.

Many commenters express concern that implementation of the example would cause a financial strain on the program. The Department disagrees. As noted above, the example does not mandate that project directors must consider a woman as being from a ''low income family'' based on her employer's religious or moral objection to contraceptive coverage in her insurance plan. The example simply affirms the project director's discretion to take that fact into consideration. Project directors are aware of long-standing flexibility when defining ''low income,'' since the 2000 regulations do not preclude project directors from deeming women who do not have contraceptive coverage because of their employer's religious or moral objection to contraceptive coverage in their insurance plans to be ''low income.'' Because the project director already has that discretion under the 2000 regulations, the Department disagrees that merely making this discretion even more explicit will result in a significant number of women being granted low income status to receive free or low cost contraceptive services from Title X projects. Commenters did not provide data from which the Department could reliably estimate how many women will seek to obtain free or low cost contraceptives from Title X providers as a result of this change and how many will then be granted ''low income family'' status by project directors.

To the extent that commenters base this objection on estimates in rules concerning religious and moral exemptions to the contraceptive coverage guidelines, the Department notes that such estimates were speculative. The Department, along with the Departments of Labor and of the Treasury, attempted to set forth various estimates concerning the number of women who would use the exemptions, but noted that they lacked adequate data to know whether those estimates were accurate. 83 FR 57536, 57550 (Nov. 15, 2018). The Departments made several assumptions that they noted were likely too high. *Id.* at 57581. And they emphasized that the estimate was not the number of women that they believed would be affected by use of the exemptions by sponsors of health insurance plans.

Even if those estimates of the women affected by the religious and moral exemption rules were accurate, the Department could not simply assume that all of those women would obtain contraceptive services from a Title X project. As noted above, the proposed additional example in this definition does not require a project director to consider a woman to be from a low income family on this basis. Project directors might conclude that women seeking to use the clarifying example have incomes that, despite their lack of contraceptive coverage, render them able to pay for contraceptive services. Moreover, it is unlikely that all women affected by the exemption rules will seek services from Title X projects. Some of those women may have family incomes under which they can afford the services. Some may choose, for other reasons, not to seek contraceptive services from Title X projects. For example, some may share their employers' objections to such contraceptives.

The Department is not aware of data from which to reliably estimate how many women will seek contraceptive services from Title X projects because the sponsors of their health plans have religious or moral objections leading them to omit contraceptive coverage from their insurance plans, but believes that any overall cost to the Title X program will be slight. With regard to low income women in general, the Department is aware that significantly less than half of such women receive services from Title X projects. In 2017, Title X projects served more than 4 million persons of whom 90% were low income persons.[66] The official poverty rate in 2016 was 12.7%,[67] therefore encompassing more than 41 million persons.[68] Thus, fewer than 10% of persons eligible for low income status in Title X projects sought and obtained Title X services. The Department estimates that an even smaller fraction of women would be affected by the exemptions provided for entities with religious and moral objections to providing contraceptive coverage. And

[66] Christina Fowler et al., *2017 Family Planning Annual Report,* Health and Human Services, (2008), *https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2017-national-summary.pdf.*

[67] Jessica Semega et al., *Income and Poverty in the United States: 2016,* U.S. Census Bureau, (Sept. 12, 2017), *https://www.census.gov/library/publications/2017/demo/p60-259.html.*

[68] U.S. Census Bureau, *Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2016,* (2017), *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk.*

the Department does not expect that the sliding scale discount discussed above would lead to a significantly greater number of women obtaining discounted contraceptives than would otherwise receive them. Their incomes will only be reduced by the cost of contraceptives, which, on average, is about $600 per year (*see* 83 FR at 57551), but the Title X sliding scale discounts span several thousand dollars between ranges. Women could thus be deemed to receive less income and still not be eligible for discounts. Finally, Title X projects pay only a fraction of the retail costs for contraceptive services discussed in the religious and moral exemption final rules.

Consequently, the Department concludes that the number of women whose employers have religious or moral objections leading them to omit contraceptive coverage from their insurance plans is small compared to the number of low income women served by Title X projects; at most, a small minority of such women will seek contraceptive services from Title X projects; the revision to the definition allows project directors to consider deeming those women as being from low income families, but it is likely that only a fraction of them will be deemed unable to pay for family planning; and the cost to the projects of contraceptive services provided or discounts offered is only a fraction of the retail costs of contraceptive services. In light of these factors, even assuming that the use of this example would lead more women to seek to use the existing ''good reasons'' exception than had previously, the Department does not believe it will lead to an unreasonable strain on the Title X program.

Even if there is an economic impact on the program, it is supported by the Title X statute. Where women are actually deemed to be from a ''low income family'' after the project director's consideration of their insurance status, the Title X statute provides for low cost or discounted contraceptive services. As discussed above, insurance status is one factor that may affect a woman's overall economic status or ability to pay for family planning services. The Department concludes it is appropriate to clarify the ''low income family'' definition through the proposed example, so that project directors may appropriately extend eligibility to such women. This helps fulfill the purposes of the Title X statute to ensure that women are not prevented from participating in the program due to their economic status.

The Department disagrees with commenters contending these revisions in the definition violate the Establishment Clause of the First Amendment. The proposed example clarifies the discretion that a project director has long had under the rules concerning good reasons why some persons may be deemed from a low income family. Specifying that a project director may consider a woman's lack of contraceptive coverage as a result of a religious exemption exercised by the sponsor of her health plan from contraceptive coverage into consideration does not violate the Establishment Clause. The example also allows the project director to consider a woman's lack of contraceptive coverage from a sponsor's non-religious moral objection, or to take any number of other non-religious factors into account as a good reason that the woman may be unable to pay for family planning services. The Department also disagrees with a commenter who argues that project directors should consider whether a woman's health plan covers abortion. Title X precludes considering abortion as a method of family planning.

Accordingly, the Department finalizes the definition of ''low income family'' without change to the prefatory text or paragraph (1), but with changes to paragraph (2) to emphasize that the project director may exercise discretion under the existing ''good reason'' exception to ''consider her insurance coverage status as a good reason why she is unable to pay for contraceptive services'' when her employer has a sincerely held religious or moral objection to providing such coverage. The final rule in paragraph (2) is also finalized with guidance for the project director in making this determination.

5. Definition of Program or Project

Summary of changes: The 2000 regulations did not define a Title X ''program'' or ''project.'' The proposed rule, at § 59.2 proposed to define ''program'' and ''project'' as interchangeable and mean ''. . . a plan or sequence of activities that fulfills the requirements elaborated in a Title X funding announcement . . .'' The proposed definition indicated that implementation of a Title X ''program'' or ''project'' may be completed by grantees, subrecipients, or partnering providers working under grantees or subrecipients who deliver comprehensive family planning services.

The Department finalizes this definition as discussed below in response to public comment by stating ''*Program* and *project* are used interchangeably and mean a plan or sequence of activities that is funded to fulfill the requirements elaborated in a Title X funding announcement; it may be comprised of, and implemented by a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area.''

This clarification establishes the Department's finding that any organization receiving Title X funds is responsible to adhere to Title X requirements.

Comments: One commenter asked the Department to alter the definition of ''Program or Project'' because many of the prohibitions against using Title X funding for abortion only legally apply to the program or project, so the commenter asked the Department to reexamine the definition to be sure that entities cannot use the definition to escape compliance with the rule's requirements. In addition, the commenter suggested that the phrase ''and may be comprised of'' does not form part of the working definition but only describes how a program or project, as defined, may be comprised. That leaves the legally operative definition in the proposed rule of ''program'' and ''project'' as being ''a plan or sequence of activities that fulfills the requirements elaborated in a Title X funding announcement.''

At the same time, the commenter expresses concern that if an entity does not fulfill all or some of the requirements of the announcement, the program or project could argue that it does not meet this definition, and thus can avoid the requirements of the rule. Instead, the commenter suggests restating the definition as ''[a]n enterprise, scheme or venture carried out or proposed to be carried out by a grantee, subrecipient(s) or a group of partnering providers pursuant to a Title X award granted by the Secretary.''

Response: The Department appreciates the commenter's observations concerning whether aspects of the program and project definition might inadvertently allow entities to avoid compliance with the requirement of the rule. The 1988 regulations stated that '''[p]rogram' and 'project' are used interchangeably and mean a coherent assembly of plans, activities and supporting resources contained within an administrative framework.'' The proposed definition was similar in referencing plans and activities. The Department agrees with the commenter that the definition should include not only a plan or sequence of activities that fulfills Title X requirements, but those that seek to

fulfill them. A program or project is one that receives Title X funding, as distinct from applications and proposed projects that are not awarded funding. In response to the commenter, the Department clarifies that, when it stated in the proposed rule that a program or project ''may be comprised of, and implemented by a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area,'' it intended those parameters to be, and those parameters will be, treated as operative parts of the definition. The Department intends to enforce all requirements of the Title X program with respect to any entity receiving a Title X grant. If an applicant cannot sufficiently show that the program will meet all the Title X requirements, then it will not qualify for a Title X grant. Consequently, the Department finalizes this definition by changing the word ''fulfills'' to ''is funded to fulfill,'' and by changing the phrase ''and may'' to '', and it may''.

6. Definition of Subrecipient

Summary of changes: The 2000 regulations do not define subrecipient. The proposed rule, at § 59.2, proposed to define ''subrecipient'' as ''any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. These entities may also be referred to as ''delegates'' or ''contract agencies.'''

There were no substantive comments under this section that are not already discussed elsewhere in the preamble to this rule. The Department finalizes this definition without change, except for minor grammatical corrections.

D. Who is eligible to apply for a Family Planning Services Grant or contract? (42 CFR 59.3)

Summary of changes: The proposed rule at § 59.3 proposed to delete the provision that was rendered void by means of the CRA joint resolution of disapproval that was signed by the President, and would make corresponding changes to the heading of the section. The Department finalizes this section with changes in response to comments concerning the applicability of this section to contracts. As revised, the section would specify that ''[a]ny public or nonprofit private entity in a State may apply for a family planning grant or contract under this subpart.''

Comments: One commenter supports the proposed language to nullify the provisions of the 2016 regulation and believes it will help improve the Title X program by making it permissible to fund organizations that do not provide artificial contraceptives. Another commenter thinks the federal government should directly fund national family planning organizations.

Response: The Department appreciates the support for the revocation of the nullified 2016 regulation. Regarding the commenter who calls for direct funding of entities that provide natural family planning, the Title X regulations already permit, and this final rule allows, such entities to be participating entities in Title X projects. For projects to receive a grant, they must provide a broad range of family planning methods and services. The Department does not prioritize providers of one specific family planning method over another. Accordingly, the Department believes the Title X program works most efficiently with grantor and grantees as defined in this rule.

As discussed above in section II.B concerning § 59.1, the proposed rule would not apply § 59.3 to contracts, and some commenters asked whether § 59.3 and other sections should apply to contracts. Section 1001 of the Title X statute specifies that, ''in the establishment and operation of voluntary family planning projects,'' the Secretary ''is authorized to make grants and to enter into contracts with public or nonprofit private entities.'' To conform § 59.3 to the scope of the statute, the Department finalizes § 59.3 with changes to the title of that section to read ''Who is eligible to apply for a family planning services grant or contract?'' Likewise, the text of § 59.3 is finalized with change to read: ''Any public or nonprofit private entity in a State may apply for a family planning grant or contract under this subpart.''

E. What Requirements Must be Met by a Family Planning Project? (42 CFR 59.5)

In the proposed rule, the Department proposed a number of revisions and additions to § 59.5(a)(1), (5), and (10) and (b)(1) and (8). Each is discussed in turn.

1. Broad Range of Acceptable and Effective Family Planning Methods (42 CFR 59.5(a)(1))

a. Acceptable and Effective Methods and Services

Summary of changes: The 2000 regulations required that Title X programs provide a broad range of acceptable and effective family planning methods that were medically approved. The proposed rule proposed to revise § 59.5(a)(1) by removing the language, ''medically approved'' and by clarifying the acceptable and effective family planning methods and services under Title X.

Comments: Many commenters oppose the proposed language because it removes the phrase ''medically approved'' as a description of the broad range of acceptable and effective family planning methods a project must provide. Some commenters state the language could reduce access to the safest, effective, and medically approved contraceptive methods, increase risks associated with promoting medically unreliable methods, place political ideology over science, and undermine recommendations jointly issued by OPA and the CDC on Quality Family Planning. Many commenters feel that the proposed language is misleading to patients and could negatively impact the quality of care provided to patients, especially to adolescents and young adults who may require hormonal contraceptive methods which have been associated with decreased rates of teen and unintended pregnancies.

Some commenters, however, support the proposed rule and point out that it will increase choices for persons served by Title X projects, allowing the government to choose the most qualified applicants instead of the applicants who happen to provide the most services.

Response: Section 1001(a) of the PHS Act requires Title X projects to ''offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods . . .).'' 42 U.S.C. 300(a). The final rule at § 59.5(a)(1) ensures that the regulatory language is consistent with the statutory language.

The Department disagrees with comments that oppose removal, from the regulatory text, of the phrase ''medically approved,'' leaving ''acceptable and effective'' to describe the family planning methods and services to be provided by Title X projects. As noted above, the Title X statute does not contain the phrase ''medically approved'' and it is far from clear what that undefined phrase requires. The Title X statute provides that Title X projects ''shall offer a broad range of acceptable and effective family planning methods and services . . . .'' 42 U.S.C. 300. That language was sufficient when Congress drafted the Title X statute, and the Department concludes that it is sufficient today. As such, the revision is clearly within the Department's statutory authority. The Department disagrees with commenters

who contend removing this language causes the regulations (or the Title X statute) to promote medically inaccurate information, or Title X to be administered based on a political ideology.

The ''medically approved'' language risked creating confusion about what kind of approval is required for a method to be deemed ''medically approved.'' Family planning methods offered by Title X projects are already offered by health care professionals, so, to that extent, those methods are already medically approved. But different medical doctors and professional organizations may differ on which methods of health care they approve, including different methods of family planning. Some family planning methods cannot be medically approved by a government agency, such as the Food and Drug Administration, because they do not fall within its jurisdiction.[69] This does not mean that such methods of family planning are unacceptable or ineffective in the view of medical sources.[70] Moreover, various medical sources may view a particular method differently, based on different criteria, and it is not clear what the ''medically approved'' standard would mean in a circumstance where medical authorities differ regarding a particular method. The statutory language of ''acceptable and effective family methods or services,'' without the phrase ''medically approved'' provides sufficient guidance to Title X projects in considering the types of family planning methods and services that they provide.

The Department does not believe that the final language of the first two sentences of § 59.5(a)(1), as finalized here, would limit access to family planning services or other necessary health care, nor lead to an increase in unintended pregnancies.

b. Projects Required To Provide a Broad Range of Family Planning Methods and Services, but Participating Entities May Offer a Limited Number of Family Planning Methods and Services

Summary of changes: The Department proposed to specify in the proposed rules that participating entities within a project would not be required to provide every method or service. The Department further proposed that, projects as a whole provide a ''broad range of such family planning methods and services,'' but not be required to provide every acceptable and effective method or service. The Department finalizes these sentences in § 59.5(a)(1) without change.

Comments: Some commenters agree with the Department that not every project or participating entity should be required to provide all Title X services, so long as the overall Title X project offers a broad range of family planning methods and services. They believe that allowing participating entities that do not offer all services will increase the pool of potential applicants, allow projects to offer a broader range of services by utilizing specialty providers, and allow the government to choose the most qualified applicants.

Many commenters express concern with the language describing the broad range of family planning methods and services that projects must provide. Some commenters say the proposed language would reduce the methods offered within a project by stating, ''projects are not required to provide every acceptable and effective family planning method or service . . . as long as the entire project offers a broad range of such family planning methods and services.'' Commenters express concern that projects will not be required to provide every acceptable and effective family planning method or service, and contend the language seems to encourage projects to not offer every acceptable and effective family planning method or service. Many commenters state that the proposed rules are inconsistent with the original intent of Title X to establish as a national goal the provision of adequate family planning services and to all those who want them but cannot afford them. Many commenters oppose the proposed language because they believe it will limit access to family planning services and other necessary health care. One commenter states that the definition will limit access to comprehensive reproductive health services, and therefore adversely impact women's ability to attain positive economic outcomes for themselves and their families. A commenter requests that the Department clarify that, even if a Title X project need not provide every acceptable and effective family planning method or service, a project must provide a broad range of contraceptive methods. Some commenters assert that the proposed rule may cause more abortions by encouraging low-efficacy methods of family planning and decreasing access to contraception and, therefore, increasing unintended pregnancies.

Many commenters express concern regarding the language specifying that participating entities within a project may offer a single method, or a very limited number of methods, of family planning. Some of these commenters suggest that this weakens the Title X program, undermining its status as a program offering comprehensive services, and prevents patients from making the best decisions about their health due to lack of information or options.

Many commenters suggest that allowing participating entities that offer limited services would divert scarce family planning dollars away from entities that provide effective and preferred methods of contraception and instead provide grants to entities that provide few, if any, methods that patients find acceptable. One commenter expresses concern that inexperienced entities might participate in the Title X program, making navigation more challenging as patients struggle to find providers that offer desired services. Some commenters contend that the proposed rule opens the potential for what they call ''fake'' women's health care facilities to receive funding from Title X, and that the proposed rule deemphasizes the importance of contraception and the full range of family planning methods.

Some commenters express concern that the language might allow for or encourage coercion, and might undermine the standard of health care service delivery and outcomes. Many commenters express concern that the rule will remove a person's choice in the selection of family planning method.

[69] *See* FDA, *Birth Control* (March 6, 2018), *https://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm. See also,* FDA, *Enforcement Story Archive* (August 7, 2003), *https://www.fda.gov/iceci/enforcementactions/enforcementstory/enforcementstoryarchive/ucm106947.htm* (''Warning Letter Issued for ''Fertility Awareness Kit''). *But see* FDA, *FDA allows marketing of first direct-to-consumer app for contraceptive use to prevent pregnancy* (August 10, 2018), *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm616511.htm.*

[70] For example, pursuant to a contract with HRSA, in March 2016, the American College of Obstetricians and Gynecologists (ACOG) launched the ''Women's Preventive Services Initiative.'' In its ''Clinical Recommendations,'' ACOG recommended that instruction in fertility awareness-based methods of family planning, and counseling, initiation of use, follow-up care, management, and evaluation of the same, be provided with no cost-sharing in health coverage. *See* Women's Preventive Services Initiative, *Clinical Recommendations Contraception,* American College of Obstetricians and Gynecologists (2018), *https://www.womenspreventivehealth.org/recommendations/contraception.* The Health Resources and Services Administration (HRSA), a component of HHS, adopted this recommendation on December 20, 2016, and added coverage of fertility awareness-based methods of family planning to its women's preventive services guidelines, issued pursuant to Section 2713(a)(4) of the Affordable Care Act (42 U.S.C. 300gg-13(a)(4)). *See* HRSA, *Women's Preventive Services Guidelines,* Health Resources & Services Administration (October 2017), *https://www.hrsa.gov/womens-guidelines-2016/index.html.* On that basis, fertility awareness-based methods of family planning could be said to be ''medically approved.''

Some commenters believe the proposed rule presents a potential threat to reverse decades of progress in reducing unintended and teen pregnancy, citing that natural family planning methods require a regular menstrual cycle to be effective, which adolescents rarely have.

Other commenters, however, assert that there is no requirement for each participating entity to provide all family planning services and that this flexibility is in line with our Nation's longstanding commitment to protecting freedom of conscience and comports with the First Amendment.

Response: The Department finalizes without change the language specifying that participating entities within a project ''may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.'' Neither the Title X statute nor the proposed rule would permit a Title X project as a whole to provide only one (or a limited number of) family planning methods and services. The Department is finalizing this rule which continues to require Title X projects to offer a broad range of family planning methods and services.

The Department appreciates concerns of commenters who believe the proposed language that says projects are not required to provide every acceptable and effective family planning method or service would reduce the range of family planning methods that Title X projects must provide, but does not believe that this is a reasonable interpretation of the proposed rule. To clarify, projects would continue to be required to offer a broad range of family planning methods and services, consistent with the statutory mandate. However, neither the plain language of the statutory requirements, nor the 2000 regulatory text, requires that Title X projects provide every acceptable and effective family planning method or service. Thus, the proposed rule and this final rule merely clarify, and make explicit, that the requirement for a broad range of acceptable and effective family planning methods and services does not mean every acceptable and effective family planning method or service. Furthermore, neither the plain language of the statute, nor the 2000 regulatory text, requires participating entities within a project to provide every acceptable and effective family planning method or service, or even a broad range of such methods or services. It is permissible under the 2000 regulations for a subrecipient within a funded project to offer only a single or limited number of family planning methods or services. *See* 42 CFR 59.5(a)(1) (''If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services.''). The same is true under this final rule. This is permissible only if the project as a whole provides a ''broad range'' of such methods and services. The final rule merely acknowledges and clarifies this reality.

The Department disagrees that requiring a broad range of family planning methods and services, while recognizing that some projects may not offer every method or service, would lead to an increase in unintended pregnancies. Similar to the 2000 regulations, this rule requires the project as a whole to offer a broad range of acceptable and effective family planning methods and services, which includes contraceptives. While the rule clarifies the broad range of family planning methods and services permissible under Title X, it also ensures Title X patients are free, without coercion, to select any of the broad range of family planning methods and services offered in a project. The Title X statute has always provided as much, and the 2000 regulations did too.

The Department disagrees with commenters opposing the language allowing participating entities to offer one or few family planning methods. The 2000 regulations explicitly permits this, stating ''[i]f an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of family planning services''; this language has been included in regulations since at least 1988. To the extent the commenters opposing this language do not find fault with the 2000 regulations, the Department sees no cause for concern over this provision. About four million patients are annually served with the current provision that allows organizations that offer only a single family planning method to participate in a Title X project. The Department now merely confirms this practice by stating that ''[a] participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.'' Therefore, the Department disagrees with the concerns expressed about including this sentence in the final rule.

The Department also disagrees that the proposed rule weakens the standing of Title X programs as comprehensive sources for family planning. The rule does not prohibit projects or providers from offering every acceptable and effective family planning method or service, so long as abortion is not considered a method of family planning. The rule simply reflects, as stated in the 2000 regulations, that Title X projects are required to provide a broad range of acceptable and effective family planning methods and services (not every such method or service), and that participating entities are permitted to participate in a Title X project even if not all of them offer every method—and, indeed, even if some participating entities within a project offer only one family planning method. The range of available family planning methods has significantly increased over the last few decades. The Department believes it may be unreasonably difficult or expensive to add a new requirement that all projects and all participating entities must offer all acceptable and effective forms of family planning. It may also be difficult for clients to access certain methods in which not all participating entities have specific training and expertise. This rule enhances the ability of individual Title X projects to offer, and clients to access, such methods, while preserving the requirement that individual Title X projects offer a broad range of family planning methods and services. The Department disagrees with some commenters who say the rule is misleading to Title X clients. This rule is substantially similar to the 2000 regulations rule in that it permits single method providers to participate in the Title X program and includes natural family planning methods as those that qualify under the ''broad range.''

The Department disagrees that the proposed and final rules authorize Title X funding for what some commenters call ''fake'' women's health care facilities. It is not clear what such commenters deem to be ''fake'' facilities, but nothing in the rule authorizes projects to use clinics that engage in fraud or allow the practice of medicine without a license. Title X projects are subject to quality oversight by the Department and are also subject to relevant State laws in the operation of health clinics.

The Department believes that permitting entities to provide services for which they have particular expertise allows greater access to family planning methods in Title X projects and contributes to quality care for patients. The final rule does not require projects to include participating entities that offer only one or just a few methods, but it continues to allow them to do so, if they deem it appropriate and consistent with offering a broad range of family planning methods and services.

The final rule, thus, clarifies and reframes, but does not create or invent the ability of a single-method entity to participate in a Title X project. The Department believes that continuing to allow such entities to participate will give people served under Title X access to specialized expertise in certain methods. Increasing client choices among family planning clinics and methods in a project is likely to decrease unintended pregnancies, not increase them, because clients are more likely to visit clinics that respect their views and beliefs and to use methods that they desire and that fit their individual circumstances.

The Department also agrees with commenters that say the final rule is consistent with principles of the First Amendment and laws that protect freedom of conscience. By allowing projects to use entities that offer a single method or limited methods—including providers that might do so for reasons of conscience—the language being finalized will, among other things, both protect the ability of health care providers and facilities with conscientious objections to providing certain types of family planning methods and services to participate in Title X projects and maintain Title X projects that offer a broad range of family planning methods and services.

c. Listing Particular Services in the Broad Range of Family Planning Services That May Be Provided

Summary of changes: The 2000 regulations recognized natural family planning and services for adolescents as some of the broad range of acceptable and effective family planning methods. The proposed rule proposed to clarify that natural family planning and other fertility-awareness based methods qualify as acceptable methods, as do contraceptives. In addition, as a mechanism for addressing infertility, the Department proposed to add adoption as a family planning service. Therefore, the Department finalizes § 59.5(a)(1) with changes to replace the word ''and'' with the word ''or'' before the phrase ''other fertility-awareness based methods.''

Comments: The Department received several comments about the listing of particular services in the broad range of family planning services that may be provided. Some commenters objected to references to natural planning or fertility awareness-based methods because fertility awareness-based methods are already offered at 93% of Title X clinics and natural family planning is already a method included in the Quality Family Planning Guidelines provided by CDC. Others object to these methods because they assert that the methods are ineffective, or at least among the least effective forms of family planning.

Other commenters object to language specifying adoption as a type of family planning service. They contend that the management of infertility, including adoption, is beyond the language and intent of the Title X statute. They also believe that including adoption would put a strain on the program, as it would redirect a large amount of Title X funds. And they assert that including adoption in the definition is contradictory because adoption is a postconception activity and the new definition states that family planning only includes preconception activities. Some commenters also assert that the Department improperly redefines the meaning of a reproductive life plan.

Response: The Department disagrees with commenters who say the rule should not mention natural planning or additional fertility awareness-based methods, and who contend the rule emphasizes those methods over other forms of family planning. As discussed in the context of the definition of family planning in § 59.2, the Title X statute itself requires projects to offer a broad range of family planning methods and services, and specifies that those methods ''includ[e] natural family planning methods, infertility services, and services for adolescents.'' 42 U.S.C. 300(a). The Department concludes that Title X projects (although not necessarily each provider or site within a project) must offer both contraception and natural family planning in order for the Department faithfully to implement Title X's ''broad range'' requirement. The proposed and final rules, far from over-emphasizing natural family planning or emphasizing it to the exclusion of contraceptives, add contraceptives to this non-exclusive list of examples of family planning methods that projects must provide. The proposed rule at § 59.5(a)(1) also includes the phrase ''and other fertility awareness-based methods'' alongside ''natural family planning.'' As discussed concerning the ''family planning'' definition, ''natural family planning'' is not defined in the Title X statute, and scientific advances have occurred in natural family planning methods in the last 40 years, so that some medical professionals now refer to related methods as ''fertility awareness-based methods.'' [71] The final rule does not emphasize natural family planning over other forms of family planning.

The definition of family planning at § 59.2 uses the word ''or'' before the phrase ''other fertility awareness-based methods,'' whereas the text at § 59.5(a)(1) uses the word ''and.'' The Department considers the word ''or'' to be more appropriate in both instances. This clarifies that by ''other fertility awareness-based methods,'' the Department is not referring to methods that are not ''natural family planning,'' nor is it requiring projects to offer natural family planning and other fertility awareness-based methods as if those are two different kinds of categories. Instead, by using the word ''or,'' the Department intends for projects to have flexibility in deciding which types of natural family planning or fertility awareness-based methods they will offer in meeting their obligation to offer natural family planning methods within the project. Therefore, the Department finalizes § 59.5(a)(1) with a change to replace the word ''and'' with the word ''or'' before the phrase ''other fertility-awareness based methods.''

The language specifying that participating entities may offer only a single method does not mention natural family planning or any other single method. Therefore, it does not emphasize natural family planning over other methods as some commenters contend. Under the final rule, single-method providers are permitted in projects whether their single method is a natural family planning method, a contraceptive method (for example, an implant), or some other family planning method. The Department disagrees with commenters' concerns that allowing single or limited method entities to participate in a Title X project limits family planning to natural family planning methods, limits what individuals may choose, or deprives individuals of methods they may choose. Those results have not occurred under the 2000 regulations, which already allow for single method participating entities.

The Department also disagrees with commenters who oppose the inclusion of adoption information as a type of infertility services offered by Title X providers. As discussed with respect to the proposed definition of family planning, the Title X statute does not define ''family planning,'' and the Department has always read the

[71] *See, e.g.,* Shawn Malarcher, et. al., *Fertility Awareness Methods: Distinctive Modern Contraceptives,* 4 Global Health: Science and Practice 13, 13 (2016), *available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4807745/pdf/013.pdf* (stating fertility awareness methods of contraception have been tested and proven effective at pregnancy prevention and safe to use).

examples it gives of family planning methods and services as being a non-exclusive list; otherwise, Title X could fund nothing but ''natural family planning methods, infertility services, and services for adolescents.'' Adoption is a method of planning the size of one's family and the spacing of children raised in one's family, and it can be used to enlarge one's family or to plan one's family in the context of infertility.

In addition, under Infant Adoption Awareness grants program, Congress specified that eligible health centers (which includes Title X clinics) should receive training on providing adoption information and referrals, and that the Secretary should encourage the same.[72] Accordingly, Title X projects may provide adoption information and referrals as a preconception family planning method, especially in the context of providing infertility services, and may provide adoption information and referrals during postconception pregnancy counseling as long as the pregnancy counseling satisfies the statutory requirement that it be nondirective. Therefore, the Department considers it appropriate to include adoption information in the non-exclusive list of services mentioned among a possible broad range of family planning methods and services a Title X project might offer. But consistent with the change finalized in the definition of ''family planning,'' the Department modifies the phrase contained in the proposed rule, ''including infertility services, including adoption, and services for adolescents'' to provide ''including infertility services, information about or referrals for adoption, and services for adolescents''.

Importantly, the proposed language in no way limits the choices of Title X clients or infringes on their views of what services to choose. The final rule does not require any Title X client to pursue adoption, natural family planning, or any other particular family planning method or service. On the contrary, as discussed above, the definition of family planning is finalized to specify that ''[f]amily planning methods and services are never to be coercive and must always be strictly voluntary.''

[72] *See* 42 U.S.C. 254c–6 (Congress authorized the Department to make grants ''for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women'').

2. Projects Shall Not Provide, Promote, Refer for, or Support Abortion as a Method of Family Planning (42 CFR 59.5(a)(5))

Summary of changes: The 2000 regulations prohibited Title X projects from providing abortion as a method of family planning. They also specified that Title X projects must provide information on, counseling regarding, and referral for, a variety of services for pregnant women, including abortion. The proposed rule, at § 59.5(a)(5), instead proposed to emphasize the duty of Title X providers to ''[n]ot provide, promote, refer for, support or present abortion as a method of family planning.'' The proposed rule would allow nondirective pregnancy counseling, but would delete the current language in that paragraph (including (i) and (ii)), which stated that ''[a] project must . . . [o]ffer pregnant women the opportunity to be provided information and counseling regarding . . . [p]renatal care and delivery; [i]nfant care, foster care, or adoption; and [p]regnancy termination'' and that a project must, ''[i]f requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling.'' *See* 42 CFR 59.5(a)(5).

At §§ 59.14 and 59.16, the proposed rule proposed more specific parameters to implement the requirement in § 59.5(a)(5) that ''[a] Title X project may not perform, promote, refer for, support, or present abortion as a method of family planning . . .'' and to implement the requirement that any pregnancy counseling provided by Title X projects must be nondirective. The proposed rule addressed in this section relates to the proposal to remove the requirement for nondirective pregnancy counseling and referral (including the obligation to counsel on, and refer for, abortion), and replace it with a prohibition in § 59.5(a)(5) on the use of Title X funds to perform, promote, refer for, support, or present abortion as a method of family planning. Comments discussing pregnancy counseling are discussed in a distinct part of this preamble, as are comments discussing the deletion of the requirement to refer for abortions. Comments discussing the prohibition on abortion referrals, and permissible referral activities in general, are discussed with regard to section §§ 59.14 and 59.16.

The Department finalizes the proposed rule in § 59.5(a)(5) with one change to make it clear that providers are allowed to provide nondirective pregnancy counseling about abortion, by removing ''present'' from the proposed list of prohibitions regarding abortion as a method of family planning.

Comments: Many commenters support eliminating the requirement that Title X family planning providers counsel for, provide information about, and refer for abortion, citing protections found in health care conscience laws and principles. Such commenters contend that the requirement in the 2000 regulations of abortion referrals, information and counseling is inconsistent with section 1008 of Title X, and with the conscience protections provided for in laws such as the Church, Coats-Snowe, and Weldon Amendments. Commenters also contend the proposed language appropriately protects and recognizes the importance of religious freedom and freedom of speech.

Other supportive commenters note that the 2000 regulations stand in the way of some organizations applying for Title X funds, or participating in Title X projects, due to the requirement for abortion referrals and information. Such commenters contend the 2000 regulations limit choice for patients, especially those who live in rural or remote areas, where faith-based and local community organizations would be more likely to apply if the abortion counseling and referral requirement were lifted.

Some commenters express concerns related to federal conscience protections, including the Weldon, Coats-Snowe, and Church Amendments, that may apply to Title X grantees and subrecipients. The Church Amendments prohibit grantees from discriminating in ''the employment, promotion, or termination of employment of any physician or other health care personnel'' or ''the extension of staff or other privileges to any physician or other health care personnel'' because ''he performed or assisted in the performances of a lawful sterilization procedure or abortion. . . .'' 42 U.S.C. 300a–7(c). One commenter asks that the final rule include similar conscience protections for health care personnel who refuse to engage in family planning research or services that are contrary to their religious beliefs or moral convictions. A commenter also requests clarification on whether this provision would require religious or pro-life groups who receive Title X funds to hire someone who disagrees with their religious and moral convictions

regarding abortion. Other commenters seek clarity on whether Title X projects must hire personnel who disagree with certain family planning methods. Some commenters state there is no need for further regulatory review to protect the rights of those who decline to participate in abortion-related services, but rather, contend there is a need to protect the rights of those who conscientiously provide and seek abortion-related services.

Several commenters disagree with the proposed rule's elimination of the abortion information, counseling, and referral requirements. Such commenters argue that withholding information about pregnancy options interferes with the patient-provider trust relationship, is contradictory to patient-centered care, and compromises the health of the patient, as well as the ability of the patient to make timely and fully informed decisions. One commenter states that some patients are surprised to hear abortion is legal and have other misconceptions about the procedure, making it imperative that comprehensive information about abortion be shared with those patients.

Some commenters contend that restricting counseling for and information about abortion in Title X projects would encroach on physicians' codes of ethics and responsibilities to patients. Many commenters state that prohibitions on abortion counseling and referral would directly conflict with the requirements or codes of ethics of medical professional associations, including the American College of Physicians and the American College of Obstetricians and Gynecologists. These associations state that patients should receive full and accurate information to inform their health care decisions. For example, commenters refer to the American Medical Association Code of Medical Ethics that providers should ''present relevant information accurately and sensitively, in keeping with the patient's preferences'' and that ''withholding information without patient's knowledge or consent is ethically unacceptable.'' Some commenters contend that the restriction on referral, and on directive abortion counseling, may put providers at risk of medical liability since a delay or failure to diagnose is one of the top three liability allegations cited by ob-gyns, who are already at an elevated liability risk compared to their colleagues.

One commenter takes the view that the rule should prohibit Title X from offering nondirective counseling on abortion altogether. The commenter proposes instead that providers should provide only life-affirming counseling to pregnant clients who consent to receive such counseling. The commenter says this approach would protect the conscience rights of certain organizations and their employees.

Response: The Department believes the requirement to provide information, counseling, and referral for abortion in the 2000 regulations is incorrect and inconsistent with a number of federal conscience protection statutes and, at least with respect to referral, with section 1008's prohibition on funding Title X projects where abortion is a method of family planning. As described in the preamble to the 1988 regulations, prior to issuance of any regulations pursuant to Title X, the Department had, since 1972, interpreted section 1008 not only as prohibiting the provision of abortion but also as prohibiting Title X projects from in any way promoting or encouraging abortion as a method of family planning. *See* 53 FR 2922, 2923. Based on the legislative history, the Department has also, since 1972, interpreted section 1008 as requiring that the Title X program be ''separate and distinct'' from any abortion activities of a grantee. Although the Department had generally permitted activities that did not have the immediate effect of promoting abortion, or the principal purpose or effect of promoting abortion, the Department also provided in its 1988 Title X regulations that ''a Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning.'' The 1988 regulations added that ''[a] Title X project may not use prenatal, social service, emergency medical, or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning.'' 53 FR at 2945.

Since that time, however, Congress has contemplated that nondirective pregnancy counseling may be offered in Title X projects. The HHS fiscal year 2019 appropriations act provides that ''amounts provided to said projects under such title shall not be expended for abortions, that all pregnancy counseling shall be nondirective. . . .'' [73] Similarly, the statute establishing the Infant Adoption Awareness program directed the Department to include ''nondirective counseling to pregnant women.'' 42 U.S.C. 254c–6.

The Department has carefully considered the provision of counseling and information about abortion in the Title X context in light of Section 1008, the appropriations riders in place since 1996 that all counseling be nondirective, public comments, policy considerations, and the Department's historical positions. As a result, the Department concludes that:

- Title X projects will not be required to refer for abortion (and, as discussed in regard to § 59.14, referrals for abortion as a method of family planning are prohibited).
- Physicians or APPs within Title X projects may offer pregnancy counseling, including counseling that addresses the option of abortion among other options, so long as the counseling is nondirective and does not include referrals for abortion as a method of family planning.
- Title X projects will not be required to offer nondirective pregnancy counseling in general, or abortion information and counseling specifically.

In stating that ''all pregnancy counseling shall be nondirective,'' Congress did not explicitly require pregnancy counseling, nor prohibit such counseling from discussing abortion if the counseling is nondirective. Unlike abortion referral, nondirective pregnancy counseling would not be considered encouragement, promotion, support, or advocacy of abortion as a method of family planning, which would be prohibited by the Title X statute and this final rule. Therefore, the approach of this final rule is more permissive than the 1988 regulations, which prohibited any counseling concerning the use of abortion as a method of family planning, but predated Congress's directive that all pregnancy counseling in the program be nondirective. Therefore, the Department finalizes without change the proposed rule's deletion of the language in § 59.5(a)(5) requiring pregnancy options information and counseling, including requiring information, counseling and referrals for abortion. Consistent with that rescission of § 59.5(a)(5)(i) and (ii), there is no requirement in the final rule that a project offer nondirective counseling or information about abortion. The rule does not, however, prohibit nondirective pregnancy counseling by physicians or APPs, even if that counseling discusses abortion.

Some commenters urge the Department to prohibit nondirective counseling concerning abortion in a way similar to the 1988 regulations. The Department acknowledges that it has the

[73] HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. 2981, 3071. This provision has been inserted into various HHS appropriations acts since first adopted in the 1996 Appropriations Act. *See, e.g.,* Consolidated Appropriations Act 2018, 115 Pub. L. 141, Div. H., 132 Stat 348, 717; Consolidated Appropriations Act 2017, 115 Pub. L. 31, Div. H, 131 Stat. 135, 521.

discretion to interpret section 1008 as it did in the 1988 regulations, but it disagrees that it must prohibit discussion of abortion in nondirective pregnancy counseling. Instead, the Department interprets Congress's directive that all pregnancy counseling be nondirective as permitting the Department to allow nondirective pregnancy counseling even if such counseling includes abortion among other options. Nevertheless, the Department also agrees, to take a phrase from the 1988 regulations, that Title X projects should not use the permission to provide pregnant patients certain information through nondirective counseling ''as an indirect means of encouraging or promoting abortion as a method of family planning.'' Title X projects and service providers must be careful that nondirective counseling related to abortion does not diverge from providing neutral, nondirective information into encouraging or promoting abortion as a method of family planning, or into referral for abortion as a method of family planning. The Department anticipates that it may provide further guidance to grantees on this issue.

Some commenters contend this rule will deprive women of the information they need about abortion or where to obtain one, but the purpose of Title X is not to provide such information. To the contrary, Congress expressly restricted the Department from funding Title X projects where abortion is a method of family planning. Title X programs, accordingly, may offer information about abortion only as part of nondirective pregnancy counseling. The primary focus of Title X remains on preconception family planning methods and services. In implementing section 1008, moreover, the Department has a history of establishing prohibitions on abortion referral, even if at other times it has allowed or required such referrals. The 1988 regulations, for example, prohibited Title X projects from providing abortion information, counseling or referrals. The 2000 regulations took a different approach by requiring information, counseling and referrals for abortion as a method of family planning in certain cases. The Department has now reconsidered this issue and believes the approach taken in this final rule is a better interpretation of section 1008, consistent with the subsequent Congressional directive that all pregnancy counseling be nondirective. Further, in the Department's view, it is not necessary for women's health that the federal government use the Title X program to fund abortion referrals, directive abortion counseling, or give to women who seek abortion the names of abortion providers. Information about abortion and abortion providers is widely available and easily accessible, including on the internet.

The Department disagrees with commenters who assert that prohibiting referrals or directive counseling about abortion violates the First Amendment rights of grantees or subrecipients. The Supreme Court explicitly rejected this claim in *Rust,* upholding the provisions of the 1988 regulations ''prohibiting counseling, referral, and the provision of information regarding abortion as a method of family planning.'' *Rust,* 500 U.S. at 193. The Court explained that the challenged provisions are permissible because they ''are designed to ensure that the limits of the federal program are observed. . . . This is not a case of the Government 'suppressing a dangerous idea,' but of a prohibition on a project grantee or its employees from engaging in activities outside of the project's scope.'' *Rust,* 500 U.S. at 193–94. The Court rejected the argument that the restrictions constitute impermissible viewpoint discrimination, and instead held the government may ''choose[] to fund a program dedicated to advance certain permissible goals,'' even when ''in advancing those goals necessarily discourages alternative goals.'' *Id.* at 194. The same principles would sustain this rule under the First Amendment. In fact, this rule is more permissive of speech than the regulations upheld by *Rust,* because this rule allows physicians or APPs to provide nondirective pregnancy counseling even if it discusses abortion, as long as the project does not promote, encourage, or refer for abortion as a method of family planning.

The Department appreciates comments that discuss how conscience laws such as the Church, Coats-Snowe, and Weldon Amendments apply in the context of the Title X program. In deciding to rescind the requirement that Title X projects counsel, provide information on, and refer for abortion, the Department concludes those requirements in the 2000 regulations are not consistent with federal conscience laws. As explained in the preamble to the proposed rule, the Department had already acknowledged this problem in the preamble to the 2008 regulations implementing these conscience protections. 73 FR 78087. There, the Department observed, ''[w]ith regards [sic] to the Title X program, commenters are correct that the current regulatory requirement that grantees must provide counseling and referrals for abortion upon request (42 CFR 59.5(a)(5)) is inconsistent with the health care provider conscience protection statutory provisions and this regulation. The Office of Population Affairs, which administers the Title X program, is aware of this conflict with the statutory requirements and, as such, would not enforce this Title X regulatory requirement on objecting grantees or applicants.'' *Id.* Although those 2008 conscience statute regulations were partially repealed in 2011, 76 FR 9968 (Feb. 23, 2011), the underlying statutes remain valid and in place, and the reasoning in the preamble to the 2008 regulations on this point remains persuasive.[74]

The Department continues to conclude that the abortion referral and counseling requirements in the 2000 regulations cannot be enforced against objecting grantees or applicants, and that such requirements cannot be used to deny participation in the Title X program or a Title X project comprised of objecting family planning providers. The 2000 regulations required that projects provide information about abortion, counsel a client about abortion if she asks for it, and refer her for abortion. However, the Weldon Amendment prohibits the federal government from engaging in discrimination against a health care entity on the basis that it does not, among other things, refer for abortion. The Coats-Snowe Amendment also prohibits the federal government and State and local governments that receive federal financial assistance—such as State and local health departments that receive Title X funds—from discriminating against a health care entity on the basis that it refuses to ''provide referrals'' for abortion or refuses to ''make arrangements for'' providing referrals for abortion. To ensure compliance with these and other federal conscience laws, this final rule does not require Title X projects to provide any nondirective counseling, information, or referral for abortion. In order to ensure compliance with section 1008, the Department affirmatively prohibits referrals for abortion. The Department thus concludes that these federal conscience protection laws, along with its interpretation of section 1008, support its decision to finalize the rescission of the requirement in the

[74] As noted in the proposed rule, the Department has issued a proposed rule that would expand the Department's enforcement ability with respect to federal conscience protection and related anti-discrimination laws. Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (Jan. 26, 2018).

2000 regulations that projects provide abortion information, counseling, and referral in § 59.5(a)(5).

The Department appreciates the concerns of commenters about other ways in which federal conscience laws might apply in Title X projects, for example, whether they require Title X providers to hire personnel with certain views or objections, or prohibit entities from firing an individual willing to perform an abortion, or who has done so in the past. The Department intends to operate the Title X program consistent with federal conscience laws, the First Amendment, the Religious Freedom Restoration Act, and similar federal laws. The Department also notes that the Title X statute itself explicitly prevents programs from receiving Title X funds where abortion is a method of family planning. Accordingly, any Title X project must ensure compliance with this final rule to receive Title X funds. The Title X statute has coexisted with federal conscience laws for over 40 years. The limitation on referral for abortion as a method of family planning in this final rule, along with the removal of the abortion counseling, information, and referral requirements, is consistent with these statutory provisions. Just as *Rust* affirmed the government's right to place such limits on the Title X program, the Department concludes that it can fully achieve the goals of the Title X program while faithfully enforcing federal conscience laws.

The Department declines the invitation of a commenter to expand these final rules to further address the protection of conscience in the Title X program. First, because the Department did not propose such provisions in the proposed rule and did not expressly request comment on the issue, it does not have the benefit of extended comment on the issue. Second, the Department does not believe further clarification of this issue is necessary in this final rule, when the federal health care conscience laws are already the subject of separate rulemaking. The Department also will not address in this rule individual qualifications for staff hiring by a Title X program for services performed before or outside the Title X program, nor accept one commenter's invitation to add provisions to implement the Religious Freedom Restoration Act as it may apply to personnel who work for entities participating in Title X projects. Rather, the Department simply notes that the Office of Population Affairs bears the responsibility for holding grantees responsible for complying with federal conscience laws in the Title X program. In addition, the HHS Office for Civil Rights has been designated to receive complaints of conscience law violations and to coordinate with the relevant program office with respect to such complaints.

The Department does not agree with the commenter who proposes that Title X providers provide prenatal care. While the Department agrees that prenatal care is important to maternal and infant outcomes, the primary purpose of the Title X program is to provide preconception family planning services. Nondirective counseling and referrals for postconception services—although not the provision of postconception health care services themselves—are the appropriate approach in the context of pregnancy, so long as they do not include referral for abortion as a method of family planning. Within a Title X project, Title X providers may not provide prenatal care because it is outside the scope of the project, but must refer for prenatal care as pregnancy makes such referral medically necessary. However, the Department encourages Title X grantees either to offer comprehensive primary health services onsite (although outside the scope of the Title X project) or to have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site.

The Department agrees with commenters that say the Department should offer more guidance concerning how projects that provide nondirective pregnancy counseling should do so consistent with applicable Title X statutory requirements. The proposed rule set boundaries on Title X projects concerning referral for, encouragement of, promotion of, advocacy for, support for, and assistance with, abortion as a method of family planning, and those boundaries would also apply to any nondirective pregnancy counseling that physicians or APPs provide within the Title X project. The proposed rule did not further specify the parameters of such counseling, for example by defining ''nondirective.'' Nevertheless, projects must comply with Congress's requirement that pregnancy counseling be nondirective, and the Department must enforce that requirement.

Therefore, the Department offers the following guidance on the requirement of nondirective pregnancy counseling. When a woman is confirmed to be pregnant, a physician or APP may provide nondirective pregnancy counseling. While all pregnancy counseling must be nondirective, in compliance with Congress's consistent direction through the HHS appropriation laws, this rule permits the physician or APP to exercise discretion on whether to offer such counseling.[75] Nondirective counseling is designed to assist the patient in making a free and informed decision. In nondirective counseling, abortion must not be the only option presented by physicians or APPs; otherwise the counseling would violate not only the Congressional directive that all pregnancy counseling be nondirective, but also the prohibitions in this rule on encouraging, advocating, or supporting abortion as a method of family planning, which the Department prohibits in order to implement, among other provisions, section 1008. Each option discussed in such counseling must be presented in a nondirective manner. This involves presenting the options in a factual, objective, and unbiased manner and (consistent with other Title X requirements and restrictions) offering factual resources that are objective, rather than presenting the options in a subjective or coercive manner. Physicians or APPs should discuss the possible risks and side effects to both mother and unborn child of any pregnancy option presented, consistent with the obligation of health care providers to provide patients with accurate information to inform their health care decisions.

Title X projects should not use nondirective pregnancy counseling, or referrals made for prenatal care or adoption during such counseling, as an indirect means of encouraging or promoting abortion as a method of family planning. They should not use such counseling or referrals to steer clients to abortion or to specific providers because those providers offer abortion as a method of family planning. Referrals for abortion as a method of family planning may not be offered. If the patient is provided a list or the contact information of licensed, qualified, comprehensive primary health care service providers (including providers of prenatal care), the list—and the Title X staff—must not identify to the woman which, if any, providers on the list offer abortion.

Referrals for abortion for emergency care purposes are not prohibited.[76]

[75] While the decision to offer nondirective counseling is subject to the discretion of physicians and APPs, this rule requires referral for prenatal care in these situations because it is a medically necessary care for all pregnant women. In any case, all pregnancy counseling must be nondirective.

[76] Similarly, in cases involving rape and/or incest, it would not be considered a violation of the prohibition on referral for abortion as a method of family planning if a patient is provided a referral to a licensed, qualified, comprehensive health service provider who also provides abortion,

Continued

Permitted referrals under this scenario include one in which a medical emergency is revealed, such as when a woman has a suspected ectopic pregnancy.[77] Because prenatal care is medically necessary for pregnancy, prenatal care referral is required and does not, under this final rule, render any pregnancy counseling impermissibly directive.

Referrals for, and information about, adoption are also permitted, as long as the counseling remains nondirective. Title X projects are not required to offer nondirective counseling or information on abortion.

Referring for adoption or prenatal care, but not for abortion, does not, in the Department's view, make pregnancy counseling directive in light of Congress's legislative directives applicable to the Title X program. Where care is medically necessary, as prenatal care is for pregnancy, referral for that care is not directive because the need for the care preexists the direction of the counselor, and is, instead, the result of the woman's pregnancy diagnosis or the diagnosis of a health condition for which treatment is warranted. Moreover, seeking prenatal care is not the same as choosing the option of childbirth. Regarding adoption referrals, in Infant Adoption Awareness grants and the Infant Adoption Awareness Training Act, Congress made clear that the provision of adoption information and referrals do not necessarily render pregnancy counseling directive.[78] By contrast, Congress has prohibited funding projects where abortion is a method of family planning. That disparate treatment in Congress's legislative directives makes it appropriate to prohibit referrals for abortion as a method of family planning, including during nondirective pregnancy counseling, while permitting (and in some instances, mandating) referrals for other purposes.

The Department disagrees with commenters who contend the rule will require health care professionals to violate medical ethics, regulations concerning the practice of medicine, or malpractice liability standards. In *Rust,* the Supreme Court upheld the prohibition in the 1988 regulations on both referral for, and counseling about, abortion in the Title X program. The Department does not believe the Court in *Rust* upheld a rule that required the violation of medical ethics, regulations concerning the practice of medicine, or malpractice liability standards. Federal and State conscience laws, in place since the early 1970s, have protected the ability of health care personnel to not assist or refer for abortions in the context of HHS funded or administered programs (or, under State law, more generally). Indeed, in *Roe* v. *Wade,* 410 U.S. 113 (1973), the Court favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared ''Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles.'' *See Roe,* 410 U.S. at 144, n.38. And in *NIFLA* v. *Becerra,* the Supreme Court upheld conscience objections to making certain statements, despite objections from professional medical organizations that similarly asserted medical ethics standards. *Nat'l Inst. of Family & Life Advocates* v. *Becerra,* 138 S. Ct. 2361, 2371–76 (2018).[79] The restrictions on referral for, encouragement of, promotion of, advocacy for, support of, and assistance of, abortion in Title X only apply to abortion as a method of family planning, not for any other reason that might give rise to malpractice liability, and the final rule has a specific provision in § 59.14(c), allowing referrals in case of emergencies.

As the Supreme Court affirmed, section 1008 and its implementing regulations are simply a matter of Congress's choice of what activities it will fund, not about what all clinics or medical professionals may or must do outside the context of the federally funded project. The Department believes that medical ethics, regulations concerning the practice of medicine, and malpractice liability standards are not inconsistent with this final rule. The Supreme Court upheld similar conditions and restrictions in *Rust* as a constitutionally permissible exercise of Congress's Spending Power. As federal law, these requirements apply to federal grantees, notwithstanding any potential State law to the contrary.

3. Removal of the Requirement for Consultation (42 CFR 59.5(a)(10))

Summary of changes: The 2000 regulations, at § 59.5(a)(10)(i), ''[p]rovide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subrecipients which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.'' The proposed rule would remove that requirement and paragraph. The proposed rule would redesignate the provision that existing or potential subrecipients be given an opportunity for maximum participation in the ongoing policy decisions of the project, from § 59.5(a)(10)(ii) to § 59.5(a)(10). The Department finalizes this part of the rule without change.

Comments: Many commenters are concerned that this change would open the door for multiple projects in one region, uncoordinated care, and a disruption in the currently successful Title X network by excluding current providers that have the expertise to provide quality services. Some commenters recommend that the language in § 59.5(a)(10) remain unchanged to preserve opportunities for local stakeholder input.

Response: The Department disagrees with commenters who challenge removing the consultation requirement at § 59.5(a)(10). Title X requires the Department to issue grants that provide a broad range of acceptable and effective family planning methods and services. Encouraging competition among applicants is conducive to achieving the goals of the Title X statute. The Department concludes that it is not necessary, and is potentially counterproductive, to require new applicants to first consult with pre-existing providers, as currently required by § 59.5(a)(10)(i), although they may choose to do so. New applicants bring fresh ideas and innovative approaches to serving patients with their family planning needs. Requiring new applicants to consult with previous or current grantees could have the

provided that the Title X provider has complied with any applicable State and/or local laws requiring reporting to, or notification of, law enforcement or other authorities and such reporting or notification is documented in the patient's record.

[77] However, as with nondirective pregnancy counseling on abortion, Title X projects and service providers must ensure that they do not, under the cover and pretext of providing such abortion referral, actually refer for abortion as a method of family planning. This is an area in which Title X projects can expect OPA monitoring and oversight and should maintain appropriate records to support such referrals.

[78] The Act calls for Title X project staff to have access to training on including adoption information and referrals ''in nondirective counseling to pregnant women'', where Infant Adoption Awareness grants are in operation. 42 U.S.C. 254c–6(a)(6)(A).

[79] *See e.g. U.S. Supreme Court Amici Curiae Brief of the American Academy of Pediatrics,* California, the American College of Obstetricians and Gynecologists, et al., *NIFLA,* No. 16–1140 (U.S. Ct) (filed Feb. 27, 2018).

unintended consequence of quashing new ideas in favor of maintaining a potentially sub-par status quo in a given locale. The Department agrees it is important that new applicants build robust community partnerships in order to expand the reach of Title X services. In some cases, awareness of a region's existing services might strengthen an application, so applicants might continue to be incentivized to consult existing grantees. But the Department will not require consultation with previous grantees as a prerequisite to application. The Department will continue to review applications based on their quality and to fund those best positioned to achieve the goals of the Title X statute and the criteria set forth in the final rule.

The Department disagrees with commenters who contend current Title X providers will necessarily be shut out as future Title X providers. Removal of this consultation requirement does not prejudge whether current grantees will continue to receive Title X grants, nor whether new applicants will receive grants. The Department, likewise, does not believe that the removal of the consultation requirement will lead to uncoordinated care. Of course, applicants may voluntarily choose with whom they partner and with whom they consult, and such coordination may strengthen an applicant's proposal. However, the Department believes the removal of this as a requirement encourages a broader range of applicants and permits innovative approaches that may not have been envisioned or supported in the past.

The Department finds no evidence to support the assertion that the final rule will drive current providers from the Title X program. Under the final rule, the government will choose from the most qualified applicants in order to achieve the statutory goals of the program. The fact that some applicants received funding in the past is not a guarantee of future funding, but neither is it a guarantee that their funding will end in the future. Encouraging new applicants in the program could improve both the quality and breadth of service within the Title X program; it does not reflect a preference for new applicants over previous grantees.[80]

4. Promotion of Access to Comprehensive Primary Health Services (42 CFR 59.5(a)(12))

Summary of changes: The proposed rule included a new § 59.5(a)(12), which stated, ''In order to promote holistic health and provide seamless care, Title X service providers should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site.'' The Department finalizes this provision with only stylistic changes to improve readability.

Comments: Many commenters state that providing comprehensive primary care onsite or through a robust referral linkage is not conducive or appropriate for Title X service providers, as many patients prefer to have their reproductive health managed by a specialist. Many commenters express that specialists have the most up-to-date knowledge of their specialty, and this is why many primary care providers in turn refer out to those specialists. Many commenters additionally indicate that this rule would create an administrative burden and result in less primary care. Many commenters state that the Department's proposed primary care requirement, including regarding a robust referral linkage, is unclear, and the regulatory text would fail to give sufficient notice to Title X grantees about the obligations under the rule.

A commenter supports the new text and expresses the view that the rule would amend the criteria for grants and increase competition to encourage a broader, more diverse, applicant pool.

Response: The Department concludes that it is appropriate to encourage Title X service providers to have comprehensive primary health services onsite (although such services cannot be billed to the Title X program, unless it serves the goals of the program) or to build a robust referral linkage with primary health providers who are in close physical proximity to the Title X site. The 2000 regulations have similar provisions at § 59.5(b)(2) and (8), requiring projects to provide ''referral to and from other social and medical services agencies'' and ''coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.'' Like the 2000 regulations, the final rule allows for a referral linkage if projects do not offer comprehensive health services onsite. The final rule adds, however, that such referral entities should be in close proximity to the service site, and places additional emphasis on projects providing services onsite. The Department considers this change appropriate to help minimize the difficulty of patients receiving needed health care outside of Title X services.

The Department believes that the connection between Title X services and comprehensive primary care decreases the overall cost and transportation challenges to obtain needed health care services identified as a result of routine family planning screening and consultation. A 2013 Child Trends Research Brief, ''The Health of Women Who Receive Title X supported Family Planning Services,'' found that 60% of women receiving care at Title X clinics report that the clinic is their primary source for health care, yet many fear they cannot address other health concerns with their family planning provider, making the need for a linkage to comprehensive primary care providers essential for women's health.[81] The report also found that women who receive care at Title X clinics generally have worse health status than women who receive services elsewhere, and that, of such women, (1) over 25% report at least 3 health concerns; and (2) one-third are obese, with an additional 29% being overweight.[82] The placing of Title X services in the context of a comprehensive primary care setting or with strong referral networks to such care is consistent with Congress's expectation. In the 1975 Title X reauthorization, the Senate Report stated: ''The Committee believes that Family Planning Services under Title X generally are most effectively provided in a general health setting and thus encourages coordination and integration into all programs offering general healthcare.'' S. Rep. No 63, 94 Cong., 1st Sess. 65–66 (1975), reprinted in 1975 US Code Cong. & Admin News 469, 528.

Since Title X family planning services are primarily limited to preconception services, it is important that Title X sites assist clients with onsite care outside of the Title X project itself, or at least with referrals to local providers, to achieve optimal preconception and general health outcomes. Since any sexually active woman of childbearing age could become pregnant, the inclusion of preconception health screenings in the continuum of family planning care is

[80] The removal of the requirement for consultation likewise does not violate the requirement in Title X section 1001(b) that ''[l]ocal and regional entities shall be assured the right to apply for direct grants and contracts . . ., and the Secretary shall by regulation fully provide for and protect such right'', which only addresses the right of certain entities to apply for direct grants and contracts. 42 U.S.C. 300(b).

[81] Elizabeth Wildsmith et al., *The Health of Women who Receive Title X-Supported Family Planning Services,* Child Trends, 1 (Dec. 1, 2013), *https://www.childtrends.org/publications/the-health-of-women-who-receive-title-x-supported-family-planning-services.*

[82] *Id.*

important for clients, whether or not seeking pregnancy. Access to comprehensive preconception health care is also important to family planning outcomes because pregnancy may stress and affect extant health conditions. Linkages to comprehensive primary health care may be critical to ensure that pregnancy does not negatively impact such conditions. In addition, the greatest risks affecting the health of a baby occur early in a pregnancy—often before a woman realizes she is pregnant—such that helping women achieve optimal preconception health is important to ensure healthy pregnancies (as well as healthy babies) should conception occur.

The Department disagrees with commenters who contend this language concerning the proximity of comprehensive primary health care cannot be implemented by Title X service providers that specialize in family planning. First, as part of providing comprehensive primary health care, clinic may employ, among other providers, health care providers who specialize in family planning. Second, the primary care provision presents two options, onsite comprehensive primary care and referrals; it does not require the provision of onsite comprehensive primary care by Title X service providers. The Department believes this clarification addresses some concerns of commenters who feared that specialized providers could not provide all the services that an individual may need. The final rule also does not permit primary care to be subsidized by Title X funds, unless it serves the goals of the program. Thus, the requirement for Title X service providers to provide onsite, or have a robust referral linkage with, comprehensive primary health services does not move Title X outside of its scope of services. Instead, the final rule makes it easier to ensure that Title X clients, particularly low income clients, have access to necessary medical services and related educational and nondirective counseling services; that screening, diagnosis, and treatment can be provided within close proximity to the clinic; and that the most needy have access to care.

5. Title X Transparency (42 CFR 59.5(a)(13)

Summary of changes: The proposed rule proposed to add § 59.5(a)(13), to require that projects ''[e]nsure transparency in the delivery of services'' by reporting certain information ''in grant applications and all required reports.'' It then outlined three types of information that would be reported: ''(i) Subrecipients and referral agencies and individuals by name, location, expertise and services provided or to be provided; (ii) Detailed description of the extent of the collaboration with subrecipients, referral agencies and individuals, as well as less formal partners within the community, in order to demonstrate a seamless continuum of care for clients; and (iii) Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients and those who serve as referrals for ancillary or core services.''

The Department adopts this provision in the final rule with four changes. First, in § 59.5(a)(13)(i), the Department replaces ''referral agencies'' with simply ''agencies'' who are ''providing referral services''. Second, the Department removes the phrase ''as well as less formal partners within the community'' from § 59.5(a)(13)(ii) and replaces it with any individuals ''providing referral services''. Third, the Department removes the phrase ''and those who serve as referrals for ancillary or core services'' from § 59.5(a)(13)(iii). Fourth, the Department makes stylistic changes to improve clarity.

Comments: Many commenters contend the transparency requirements would add administrative burden and costs to projects, stating that programs lack familiarity with policies, referral practices, or services offered by their subrecipients. Some commenters contend that these requirements will discourage qualified entities from applying for Title X grants and will put Title X grantees, in particular programs with larger referral networks, in the overly burdensome position of providing oversight for programs that provide non-Title X services. One commenter suggests that this rule would limit grantees' referral networks and clients' health care choices and would pose a special burden to larger grantees. Many commenters state the new reporting requirements for grantees would take time away from staff who might otherwise be engaged in patient care. Commenters also state that the Department already has a level of transparency in place, complete with access to subrecipient information, and that the proposed language creates a disincentivized and burdensome outcome for providers to continue collaborations.

The Department also received comments on whether and how to include referral agencies in these requirements. One commenter states that the Department should require documentation from referral agencies to ensure that referrals are not used to promote abortion. Other commenters state that the referral agencies, which receive no Title X funding, should not be subject to these reporting requirements.

Some commenters state that the regulatory text is unclear and inconsistent, and fails to provide sufficient notice of obligations under the rule. They point out that it does not define ''less formal partners'' and does not express a distinction between ''ancillary'' and ''core'' services. They contend the rule unreasonably assumes an individual physician would know the myriad revenue streams that a large system receives.

Response: The Department disagrees that the rule will impose an inappropriate administrative burden or cost on projects. The reporting requirements would expand transparency surrounding Title X services. The proposed rule would require applicants to provide certain information in their applications, required reports, and in response to performance measures. The information required would include the name, location, expertise and services provided or to be provided by the subrecipient/referral agency/individual; a detailed description of the extent of the collaboration with subrecipient/referral agency, in order to demonstrate a seamless continuum of care for clients; and a clear explanation of how the grantee will ensure adequate oversight of, and accountability for quality and effectiveness of outcomes by, subrecipients. This information is necessary to ensure that Title X projects are achieving the goals of the program and expending grant funds properly.

The Department also disagrees with the suggestion that the transparency requirements disincentivize collaborations. The fact that grantees need to describe subrecipient and agencies or individuals providing referral services by name, location, expertise and services provided or to be provided does not deter those collaborations. Grantees should already know the details of those collaborations if they are important to the success of their projects. Understanding and being able to describe the details of collaborations is important to ensure the collaborations help the project achieve the goals of the program and comply with all applicable program requirements.

The Department appreciates the responses to its request for comment specifically on whether a referral agency should be subject to the same reporting requirements as a grantee and/or

subrecipient.[83] After carefully considering the comments on this issue, the Department concludes that the regulations should apply differently to referral agencies than to subrecipients of funding. A subrecipient ''provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient.'' As such, the subrecipient functions as a part of the Title X program in providing preconception family planning services. Referral agencies do not receive Title X funds to provide Title X services. The Department, thus, has concluded it will not use these rules to hold referral agencies to the same requirements that are expected of grantee and subrecipient entities. Grantees and subrecipients must provide certain information regarding their referral network, as described elsewhere in this rule, but since referral entities do not receive Title X funding, they are not required to comply with the requirements of this final rule.

The Department also concurs that the phrase ''ancillary or core services'' may not have been clear. Therefore, the Department does not include the phrase ''and those who serve as referrals for ancillary or core services'' in § 59.5(a)(13)(iii) of the final rule. The Department also agrees with commenters who say it is difficult to understand what is meant by ''less formal partners.'' The Department believes it is sufficient to include subrecipients and referral agencies and individuals in the explanation of collaborations, so the phrase ''as well as less formal partners within the community'' will likewise not be included in § 59.5(a)(13)(ii) of the final rule.

6. Encouragement of Family Participation (42 CFR 59.5(a)(14))

Summary of changes: The proposed rule would add § 59.5(a)(14), a new requirement that projects ''[e]ncourage family participation in the decision of minors to seek family planning services and ensure that the records maintained with respect to each minor document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).'' The Department adopts this language with changes to clarify that family participation is encouraged for all patients, including, but not exclusive of, minors in the final rule.

Comments: Many commenters express concern that this language undermines patient confidentiality and access to care by placing increased pressure on adolescent patients to involve their family, and may possibly cause patients to avoid seeking care. Many commenters state this requirement creates barriers for young people to obtain care by imposing several new, but in their opinion, antiquated requirements on providing care to minors, especially through screening the adolescents for STDs or pregnancy.

Many commenters express concern that providers will be confused about their obligations. They assert this requirement is not responsive to the CDC/OPA Quality Care Guidelines, and state that it runs afoul of the Title X regulations that require providing services in a manner that protects patients dignity and ensures patient choices are entirely voluntary. Many commenters suggest that involving family members is not always advisable or realistic, and could cause conflict with some State statues or regulations that allow minors to make decisions about their health care, including contraception. One such commenter suggests that this paragraph be stricken or at least clarified further.

Many commenters feel that clinicians should not be required to take specific actions to document attempts to involve family members, as this would undermine patient-provider relationships and is unnecessary and excessively burdensome. Alternatively, commenters recommend that the efforts and funds from Title X programs would be better used to support training for providers on the best methods to encourage family involvement consistent with minor patient's confidentiality rights, health needs, and best interests.

Some commenters support the language requiring, and documenting, the encouragement of family participation, saying it is an appropriate clarification of the Congressional mandate for the program. Several commenters state that the requirement is consistent with the statutes and Supreme Court jurisprudence on parental rights. One commenter states that the encouragement of family participation and other reporting requirements provide an appropriate layer of protection for children to ensure Title X agencies are considering circumstances in which minors may be suffering abuse. One commenter states that the language does not have a chilling effect on access to Title X health services. Other commenters commend the Department's proposed language and suggest that encouraging parental involvement should always be the standard for any health care services provided to a minor.

Response: The Department realizes that the Title X statute is clear that family participation should be encouraged for all patients who access family planning services, and not merely minors. Congress requires that ''[t]o the extent practical, entities which receive grants or contracts under this subsection shall encourage familiy [sic] participation in projects assisted under this subsection.'' 42 U.S.C. 300(a). However, pursuant to annual appropriations provisions, Congress directs additional specific requirements with respect to the encouragement of family participation in the decisions of minors to seek family planning services: ''None of the funds appropriated in this Act may be made available to any entity under title X of the PHS Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services . . . .''[84] To ensure compliance with these requirements, the final rule requires Title X service providers to encourage family participation in the decision of minors and others to seek family planning services. It also requires providers to document, in the records maintained with respect to each minor patient, the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).[85] The Department believes that the rule clarifies the steps the Title X providers must take, consistent with governing law, to encourage family participation, especially with respect to minors.

The Department disagrees that the rule causes conflict with State statutes and other Title X regulations. As noted above, the rule specifically implements several federal statutory requirements by requiring encouragement of family participation in family planning decisions while making allowance for instances where such encouragement would not be appropriate. Requiring

[83] The Department proposed to define ''subrecipient'' as ''any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. These subrecipients have entered into binding agreements or other financial relationships with Title X grantees to provide Title X services in a given State or community. A ''[s]ubrecipient'' may also be referred to as a ''delegate'' or ''contract agency.'' These entities receive Title X funds to provide Title X services, and are subject to the Title X statute and regulations.

[84] HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[85] As noted below, suspecting child abuse, child molestation, incest, or the like and reporting it to the appropriate authorities, consistent with State or local reporting or notification laws, would constitute a good reason not to encourage family participation.

Title X projects to encourage family participation in the decision of unemancipated minors to seek family planning services does not require, and is not the equivalent of, parental notification or family participation. Rather, the ordinary meaning of Congress's requirement would be for a provider to converse with a minor (or other) patient in the course of care, and in an appropriate way, encourage family participation in the patient's consideration of family planning methods and services. This requirement is consistent with the ordinary understanding that communication between health care providers and patients is essential to providing quality and effective care. Congress is not required to fund projects where minors (or other patients) are given subsidized family planning but not encouraged to involve their families in their family planning decisions. To the extent that there is conflict between the Title X statutory (and regulatory) requirements and any requirements of State law, the federal requirements would apply to the recipients (and subrecipients) of Title X funds.

The Department understands some commenters' concerns about the need to maintain patient confidentiality. The Department agrees that Title X providers must continue to comply with laws concerning patient confidentiality, including those specifically pertaining to the confidentiality of minors with respect to Title X services. Health care providers already have conversations with their patients and document those discussions in patient records, while maintaining patient confidentiality. More broadly, such health care providers in the Title X program are also already required to encourage family participation where practical by the statutory directives adopted by Congress. This provision merely implements that requirement. With respect to minors, the Department believes that Title X projects and participating entities can comply with the rule's requirement to encourage family participation and to document such encouragement, or to note the reason why that was not appropriate, without infringing on patient confidentiality.

To those commenters who contend that encouraging family participation imposes barriers to the care of minors, the Department would point out that Congress made a different judgment. Congress requires that, ''[t]o the extent practical'', Title X grantees ''shall encourage familiy [sic] participation in projects assisted under this subsection.'' 42 U.S.C. 300(a). Similarly, specifically with respect to minors, Congress has made it a condition of funding that an applicant for a Title X award ''certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services.'' HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090; Consolidated Appropriations Act 2018, Public Law 115–141, Div. H, sec. 207, 132 Stat. 348, 736. Congress clearly did not anticipate a meaningful barrier when it enacted these requirements. Moreover, encouraging family participation is not the same as requiring family participation. The rule also allows appropriate discretion for health care professionals with respect to the requirement to encourage family participation where, for example, family participation may present a serious risk to the minor, such as when child abuse or incest is suspected. The rule simply requires Title X providers to document, in the patient's records, the reasons why family participation was not encouraged and, consistent with applicable local law, to report any suspected abuse to the relevant authorities.

The Department disagrees with those who contend the rule may compromise the provision of patient-centered care or the protection of the patient's dignity. The Department believes that involving parents in general, and in family planning decision-making in particular, can improve behavioral consistency with health recommendations for an adolescent. There is evidence that parent-child communication about family planning decisions increases the likelihood that the adolescent will consistently make healthier choices.[86]

For all these reasons, the Department considers it appropriate to finalize the proposed rule concerning encouragement of family participation, with the clarification noted above.

7. Provide for Medically Necessary Services (42 CFR 59.5(b)(1))

Summary of changes: The proposed rule would amend § 59.5(b)(1) to require that any referrals to other medical facilities be made consistent with § 59.14(a), which would bar referral for abortion as a method of family planning. The department finalizes 42 CFR 59.5(b)(1) with stylistic changes and to change the phrase ''when medically indicated'' to ''when medically necessary.'' The finalized provision requires Title X projects to:

Provide for medical services related to family planning (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and referral to other medical facilities when medically necessary, consistent with § 59.14(a), and provide for the effective usage of contraceptive devices and practices.

All comments concerning this section are addressed in the section of this preamble that discusses new § 59.14(a).

8. Provide for Coordination and Referral, Consistent With Prohibition on Referral for Abortion (42 CFR 59.5(b)(1))

Summary of changes: The 2000 regulations state that projects must ''[p]rovide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.'' The proposed rule would amend this provision by requiring that any referrals be consistent with § 59.14(a), which would bar referral for abortion as a method of family planning.

The Department's discussion of and response to other comments relevant to this language are incorporated in the section of the preamble discussing proposed § 59.14(a).[87]

The Department finalizes this language without change, except for corrections in punctuation.

F. Criteria for Selection of Grantees (42 CFR 59.7)

Summary of changes: At § 59.7 of the proposed rule, the Department proposed to revise the criteria for the selection of grantees set forth in the 2000 regulations. The 2000 regulations set forth seven criteria for the Department to take into account, including the four criteria established in PHS Act section 1001(b). Those four criteria are included in the 2000 regulations and are similar to the PHS Act wording: (1) ''The number of patients to be served, and, in particular, the number of low-income patients,'' (2) ''the extent to which

[86] Patricia Dittus et al., *Parental Monitoring and Its Associations with Adolescent Sexual Risk Behavior: A Meta-analysis,* 136 Pediatrics e1587–99 (2015).

Tianji Cai et al., *The School Contextual Effect of Sexual Debut on Sexual Risk-Taking: A Joint Parameter Approach,* J Sch Health. 2018; 88: 200–207 (2018). *library.nih.gov/pubmed/29gov.ezproxyhhs.nihlibrary.nih.gov/pubmed/29399838* or *https://www.ncbi.nlm.nih.gov/pubmed/29399838.*

[87] As discussed above, in § 59.5(a)(12) the Department is finalizing requirements concerning the relationship between Title X service providers and comprehensive primary health services. The Department is also maintaining the requirement for coordination and use of referral arrangements in in § 59.5(b)(8), but qualifying that requirement with the more specific requirements set forth in in § 59.14(a).

family planning services are needed locally,'' (3) ''the relative need of the applicant,'' and (4) an applicant's ''capacity to make rapid and effective use of such assistance.'' The 2000 regulations also added three additional criteria not listed in the PHS Act: (5) The ''adequacy of the applicant's facilities and staff,'' (6) the ''relative availability of non-federal resources within the community to be served and the degree to which those resources are committed to the project,'' and a catch-all criterion considering (7) ''the degree to which the project plan adequately provides for the requirements set forth in these regulations.'' The proposed rule would restructure these requirements into five parts: first, in paragraph (b), a consideration of whether the applicant proposes to satisfy the requirements set forth in the regulations, and then, in paragraph (c), the four criteria set forth in section 1001(b), elaborating on each one to indicate how the Department would implement them. The proposed rule would delete the remaining two paragraphs of the 2000 regulations discussing cost allocations for projects as determined by the Secretary.

The Department finalizes this section with changes in § 59.7(c)(2) to address concerns raised by certain comments regarding an applicant's ability to procure a broad range of diverse subrecipients. In the final rule, the Department also retains § 59.7(b) and (c) of the 2000 regulations, which the proposed rule would have deleted, but redesignates them as § 59.7(d) and (e). Finally, several stylistic changes are made to improve clarity and readability of the application review criteria.

Comments: Several commenters state the rule significantly alters the existing program grant review criteria, undermining the usefulness of the criteria for the purpose of differentiating the best applications and best uses of Title X funds. Some commenters state that the new, shorter list of criteria contributes to greater Department leeway in making decisions about awards that do not focus on the effectiveness of the family planning care. One commenter contends that the new criteria will limit the number of qualified and experienced health care providers who can compete for funding. One commenter states the Department provides no justification or rationale for the requirement for new and inexperienced partners. The commenter laments that the wording of the rule appears to require projects to partner with new organizations each year—an unworkable proposition because the pool of new providers is limited.

Some commenters state the rule will unconstitutionally give an advantage to religious groups due to the second factor of the grant review process criteria stating that preference will be given ''especially among a broad range of partners and diverse subrecipients and referral individuals and organizations, and among non-traditional Title X partnering organizations.'' Some of these commenters express concern that the ''diverse'' and ''non-traditional'' organizations the Department is referring to are faith-based providers or religious entities that oppose abortion and some or all forms of contraception. The commenters state that these organizations have been previously ineligible to receive Title X funds but would now be eligible under the new criteria. One commenter argues the rule provides no evidence supporting the idea that there are many ''non-traditional'' organizations and different kinds of new subrecipients that could cycle into Title X projects and improve low income patients' access to high-quality family planning services.

Some commenters state the rule will not increase competition and rigor among applicants, encourage broader and more diverse applicants, or better ensure quality applicants are selected. Rather, they contend the rule will curtail the current wide reach of Title X by allowing funding to organizations that do not provide comprehensive pregnancy counseling. A few commenters state that there was no evidence that a change in the application review process or additional diversity among applicants is necessary.

Some commenters note that the existing network of Title X primary grantees and subrecipients has been relatively stable over time and has developed deep expertise and experience in family planning that profoundly benefits the communities they serve. They believe the rule will jeopardize the existence of well-developed, proven-effective programs that are based on the best clinical standards, scientific evidence, and care. One commenter asserts that, although the Department states there will be increased competition for funding, the changes set forth in the proposed rule will only change the types of entities applying for these funds, inviting organizations to apply that have no interest in fulfilling the statutory program mandate to provide a broad range of effective family planning methods and services.

Some commenters express concern regarding how much weight will be allocated to each criterion, and whether preferences may be established for Title X projects that do not provide a full scope of scientific, medically based care, citing providers of natural family planning and other fertility awareness-based methods. One commenter expresses a belief that sites providing abortion services will be disqualified and other sites that offer natural family planning and fertility awareness-based methods will be preferred.

One commenter supporting the proposed rule describes the process for evaluating applicants as thorough, and is in favor of requiring applicants to demonstrate their ability to comply with regulations, especially in terms of separation of funds and transparency of activity. The commenter adds that this requirement likely would reduce the potential for misuse of funds. One commenter argues grant applicants should be required to provide written assent to all relevant statutory and regulatory requirements, and should submit all relevant organizational documents, such as personnel manuals, client guidelines and protocols, in order to demonstrate that the organization has a pervasive policy framework and organizational culture consistent with the law and the final rule.

Several commenters state the Department will have unchecked discretion to prevent applications from reaching the objective review process that now governs the awarding of grants, putting the Department in complete unfettered control of which applications will be a part of the objective review process. Such commenters state that, historically, the process has hinged on the evaluation of objective review panels, but the new assessment would be subjective and non-transparent, and would give the Department discretion to block any applicant from reaching the competitive review process, perhaps for political purposes. Several commenters state the criteria are unclear and vague, and ask the Department to specifically and clearly state the criteria with which it will review applicants before they reach the objective panel review. One commenter contends the Department is bypassing the regulatory process to add new criteria, and says the rule will include a subjective standard without oversight.

A few commenters state that, in applying these criteria retroactively to grantees with current grants at the time the final rule goes into effect, the rule would undermine the fairness of the funding opportunity announcement (FOA) and thwart the award process in which applicants were scored on criteria about which they were aware at the time of their applications. The commenters contend that imposition of

these measures well after the application due date of the previous FOA would create a fundamentally unfair scoring process with respect to that FOA and would unjustly provide funding to organizations not capable of providing the full range of comprehensive services that has long been the benchmark of Title X care.

Response: The Department generally agrees with commenters who support the proposed language of § 59.7 as providing a thorough process to ensure applicants demonstrate their ability to comply with regulations and avoid misuse of funds.

Proposed § 59.7(b) would require Title X applicants to clearly address how their proposal will satisfy the requirements of this regulation, in order to proceed to the competitive grant review process. As a result of confusion by some commenters, the Department provides additional clarity with further detail related to the requirements for compliance with this initial screening. An applicant would be required to describe its plans for affirmative compliance with each requirement of the Title X regulations, as explicitly defined by the Department in the funding announcement. For example, this would include not only demonstrating physical and financial separation from abortion as a method of family planning (when compliance with such requirement becomes required), but also explaining how the applicant will provide a broad range of acceptable and effective family planning methods and services. The funding announcement will clearly describe how applicants should address this requirement, including any documentation that is necessary to demonstrate affirmative compliance with each of the regulation requirements. The Department will implement these requirements to better direct Title X funds for family planning projects, to prevent misuse of funds, and to save taxpayer dollars by only sending qualified applications to the costly and time consuming competitive review committee. Once the applicant successfully demonstrates affirmative compliance with the Title X regulations (a yes/no issue), the Department will consider each applicant competitively according to the criteria set forth in the regulation.

In response to a commenter suggesting that applicants be required to submit additional documentation such as personnel guidelines and documents regarding the organizational structure of applicants, the Department agrees that submission of such documents may be included to support an application, but will not require it. The Department concludes that such a requirement may be overly burdensome. Applicants will be required to demonstrate they will achieve the goals of the program and meet the statutory and regulatory criteria, but the Department declines to add the additional documentation requirements suggested by the commenter.

The Department acknowledges the confusion expressed by commenters on the meaning of the phrase ''a broad range of partners and diverse subrecipients and referral individuals and organizations, and among non-traditional Title X partnering organizations'' in § 59.7(c)(2) of the proposed rule. Although most such commenters objected to the need for new partners, the Department notes that it does not intend that grant funds be designated to referral individuals or referral organizations, since such referrals are made without any monetary exchange. Grant funds would only be provided to ''non-traditional Title X partnering organizations'' if they are subrecipients in a Title X project. The Department further clarifies that it does not intend that grantees must change subrecipient relationships each year, but that grantees make ongoing efforts to expand the network of partners throughout the service area, especially with respect to nontraditional partnering organizations. The Department additionally clarifies that it does not expect grantees who plan to provide all family planning services themselves, to now designate that these services be provided by subrecipients. The Department wishes to spur innovation and more extensive service, but does not wish to limit grantees' flexibility. However, if grantees implement a model in which they partner with subrecipients for services, the Department wants to emphasize that a broad range of subrecipients be partners, including those who are nontraditional organizations, but this does not necessarily mean that such subrecipients will be new providers in the Title X program. Finally, the Department adds the phrase ''as applicable'' following the ''broad range of diverse subrecipients in recognition of and to allow for grantees, such as community health centers, who may choose to directly provide services and not use any subrecipients. To clarify this provision and resolve the concerns of many commenters, the Department modifies the language of § 59.7(c)(2) in the final rule to read as follows: ''The degree to which the relative need of the applicant for federal funds is demonstrated in the proposal, and the applicant shows capacity to make rapid and effective use of grant funds, including its ability to procure a broad range of diverse subrecipients, as applicable, in order to expand family planning services available to patients in the project area.''

The Department rejects the claim by some commenters that the criteria set forth in the rule gives an unconstitutional advantage to religious groups. Neither the proposed language, nor the language of the final rule (including § 59.7(c)(2)), mentions religious groups nor expresses a preference in favor of them. The Department's focus in implementing Title X is on providing and expanding the provision of services to low income, unserved or underserved patients in a timely manner. The Department welcomes applications from faith-based organizations as well as secular non-profit entities. With respect to the criteria in § 59.7(c)(2), the Department would favor those applicants that can meet the needs of patients, especially those who are unserved and underserved, seeking family planning services, while complying with the statutory and regulatory requirements of the Title X program. The Department encourages Title X applicants to develop innovative strategies to meet the family planning needs of the various populations in their proposed service areas. Diversity in the range of partners included in applicants' proposals is but one factor among many that the Department will consider in reviewing applications.

The Department disagrees with commenters who contend the criteria in § 59.7 will diminish the program's effectiveness. Rather, these criteria will assist the Department in ensuring that the statutory requirements of the Title X program are met, the program is serving patients as Congress intended, gaps in services (or populations served) are closed, and providers are free to explore and test new ways to better provide service to patients.

The Department similarly disagrees with commenters who fear the rule, and the review criteria in particular, will exclude some applicants, especially those who provide abortion or those who have long experience with the program. No provision in Title X or in the proposed or final rule prevents abortion-providing organizations from applying for, and receiving, Title X funding, so long as the organization meets this rule's requirements with respect to the proposed Title X project, including physical and financial separation, and not providing,

promoting, or referring for abortion as a method of family planning in the Title X project. Nothing in § 59.7 excludes experienced Title X providers from continuing to compete on a level playing field for Title X funds. In fact, some review criteria might be more easily met by applicants with experienced and established networks. The Department intends for all funded applicants, both new and those who are experienced Title X providers, to improve or expand the quality and scope of overall service to clients, as a result of following the criteria set forth in these final rules.

The Department also disputes the assertion by some commenters that an emphasis will be placed on natural family planning over other methods. In the final rule at § 59.7(c)(1), the Department clearly and specifically requires every Title X project to provide a ''broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).'' The Department emphasizes that Section 1001 of the Title X statute includes natural family planning in its non-exclusive list of family planning methods and services. *See* 42 U.S.C. 300(a). The Department's definition of family planning recognizes the broad range of statutorily acceptable services by ''including contraceptive methods, and natural family planning or other fertility awareness-based methods.'' Accordingly, nothing in the criteria set forth in § 59.7 expresses a preference for applicants that offer natural family planning or other fertility awareness-based methods methods—they simply require each project to offer both contraceptives and natural family planning or other fertility-awareness based methods.

Consistent with the Department's historic processes, the weight attached to each criterion is not established in this rule. This is not only consistent with how the Department has operated, but also with the process of most other grant funding programs. The Department reserves the discretion to set forth more specific weights for each criterion in funding opportunity announcements.

The Department has not given itself unchecked discretion to disqualify applications in this rule. First, the Department is bound to maintain the integrity of the program and to implement the program in such a manner as to ensure compliance with statutory requirements. All provisions in this rule seek to achieve that purpose. The 2000 regulations afforded the Department significant flexibility in determining criteria for awards. In the revised version of § 59.7, paragraph (b) sets forth an overarching requirement that each applicant clearly address how the proposal will satisfy the requirements of the regulations and describe the applicant's plans for affirmative compliance. That paragraph, far from giving the Department unconstrained discretion, ensures that projects will comply with the provisions of the applicable statutes (which are embodied in the regulation) and the regulations themselves. It also increases the efficiency of the review process by only expending Department resources for the competitive review panel to review applications that meet the minimum requirements for the program.

Second, paragraph (c) of § 59.7, as revised, does not set forth any novel flexibility or discretion not already provided by the Title X statute and available under the Title X regulations. The 2000 regulations, like section 1001(b) of Title X, simply state the Department shall ''take into account'' those factors. The statutory list of factors is not exclusive. And the Department has periodically described, in funding opportunity announcements and its grants policy, other criteria applicable to proposals, paying due attention to consistency with the Title X statute and regulations. Section 59.7(c) of this final rule states that applicants ''will be subject'' to those criteria, again leaving the Department some discretion to describe additional criteria. But in all events, the Department recognizes that such criteria must be consistent with any applicable statutes and regulations. And here, the new regulatory criteria are consistent with the requirements set forth in the Title X statute.

Third, as is true throughout the Department, Title X grants are awarded through a merit-based grantmaking process consistent with the Department's grants policy, and in accordance with the Executive Branch's Uniform Administrative Requirements and the Department's own grants regulations. In this competitive process, eligible applications are reviewed by a panel of independent reviewers and evaluated based in part on criteria in the Title X program regulations, and published in the funding opportunity announcement. In addition to the independent review panel, Federal staff review each application for programmatic, budgetary, and grants management compliance. Finally, applications recommended for funding are evaluated, in accordance with 45 CFR 75.205, for risks before an award is issued.[88]

The Department does not agree with commenters that it will assert unchecked discretion to arbitrarily dismiss applications before reaching the independent review panel. For example, as stated in paragraph (b) of the final rule, the Department has committed to ''explicitly summarize each requirement of the Title X regulations . . .'' or provide the entire regulation with which the applicant must demonstrate compliance, and has explained that applicants must ''describe its plans for affirmative compliance with each requirement.'' These requirements, which focus on regulatory provisions with which grantees must comply, provide meaningful parameters to the Department's discretion. Failure by an applicant to clearly demonstrate compliance with Title X regulations would constitute a fatal flaw to an application for Title X funds.

The Department also notes that broad discretion is granted to it by the Title X statute when selecting between potential grantees. The 2000 regulations acknowledged this discretion when they stated that ''the Secretary may award grants for the establishment and operation of those projects which will in the Department's judgment best promote the purposes of Section 1001.'' 42 CFR 59.7(a). Requiring applicants to establish compliance with Title X regulatory provisions is important to providing the Department with an informed baseline for exercising this discretion. As noted above, these regulatory provisions ensure compliance with the statutory framework and, thus, provide useful information for assessing applications both before and within the competitive grant review process. The Department believes that receiving this information will enable the Department to more efficiently and effectively review the significant number of applications for Title X funding, as well as provide important information to the independent review panel. Accordingly, the Department finds that the final rule reflects a proper and effective exercise of the Department's grant discretion bound by the statutory and regulatory text.

[88] 45 CFR 75.204 (''HHS funding agency review of merit of proposals'', provides that ''[f]or competitive grants or cooperative agreements, unless prohibited by Federal statute, the HHS awarding agency must design and execute a merit review process for applications. This process must be described or incorporated by reference in the applicable funding opportunity (*see* appendix I to this part.) *See also* § 75.203.'')

In sum, the Department believes the final rule functionally and appropriately limits the Department's discretion by requiring that applicants be subject to the criteria set forth in § 59.7(c), and that the discretion the Department retains under § 59.7 to consider other factors is not fundamentally different from the non-exclusive lists of factors set forth in the 2000 regulations. The Department believes that this final rule will help ensure reliability and certainty in the grant selection process, while maintaining an open process similar to the selection process for other grants at the Department. In pursuing these ends, the Department continues to focus on ensuring compliance with the statutory Title X requirements,[89] including the program integrity provisions referenced throughout this preamble; expanding the type and nature of the Title X providers and ensuring the diversity of such providers so as to fill gaps and expand family planning services offered through Title X; and using review criteria as a meaningful instrument to assess the quality of the applicant and the application. The Department believes that these goals, which are consistent with the Title X statute and similar to the approach taken in the 2000 regulations, are best achieved by finalizing § 59.7 as set forth in this final rule.

In response to a commenter who requests that an additional criterion be added to § 59.7(c) to consider whether there is a family planning gap in the community, the Department appreciates the concern. But, as part of the final rule, § 59.7(c)(4) already states the Department will consider ''[t]he extent to which family planning services are needed locally. . .'' and whether the applicant proposes innovative ways to provide services to unserved or underserved patients. The Department believes that the community's need—including any family planning gaps in the community—is already adequately addressed in that criterion. Furthermore, in response to comments cited earlier that emphasize the value of Title X as the sole federal program dedicated to funding family planning services for low income individuals, the Department adds a reference to low-income patients to the criterion in § 59.7(c)(3) in order to accentuate the obligation of Title X projects to serve low-income patients and populations.

The Department agrees with the concerns of commenters who ask that the application criteria not be effective with regard to a FOA that has already been published, and where applications have already come due, prior to the effective date of this final rule. The Department agrees that applicants should know the criteria on which review of their applications will be based. Therefore, the Department will establish compliance dates for these provisions so that § 59.7 and the criteria set forth therein will be applied only to future FOAs issued after the effective date of this final rule, consistent with the effective dates and compliance dates established in this final rule. To the extent these criteria are relevant to applications for continuation awards under previously awarded grants, § 59.7 will also apply if those continuation award applications are due after the effective/compliance date, *i.e.,* more than 60 days after the publication date of the final rule. As discussed below, the Department is establishing compliance dates for other provisions of the final rule in the transition provision, § 59.19, so language clarifying the compliance date for § 59.7 is set forth in that provision.

The proposed rule would have deleted current § 59.7(b) and (c) from the Title X regulations. These provisions concern the amount of an award with respect to a project's estimated costs. The Department did not receive comments concerning the proposal to delete these paragraphs. Upon further consideration, however, the Department has determined that it is appropriate to retain these two paragraphs from the 2000 regulations. In section 1006(a), Title X provides that, while the Secretary shall determine the amount of any grant, no grant may generally be made for less than 90% of its costs. The Department believes that these current provisions in the Title X regulations—which reiterates this requirement and provides that no grant may be made for an amount equal to 100% of the project's estimated costs—express statutory requirements for the Title X program. The Department believes explicitly maintaining these statutory parameters in the Title X regulations provide helpful clarity for Title X grantees. Therefore, the Department is not finalizing the proposal to delete these two paragraphs from the 2000 rule, and this final rule will retain the paragraphs, redesignated as paragraphs (d) and (e).

G. Confidentiality (42 CFR 59.11)

Summary of changes: The 2000 regulations required that all information obtained by project staff about individuals must be held confidential and not disclosed without the individual's documented consent, with limited exceptions required by law. The proposed rule, at § 59.11, would clarify that confidentiality concerns cannot be the basis for failure to comply with legal requirements to report or provide notice of certain criminal activity. With the proposed amendment, section 59.11 would specify that ''[a]ll information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality; concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.''

The Department adopts the modification to this section without change, except for corrections in punctuation.

Comments: Many commenters assert that medical professionals are deeply committed to protecting patients who may be victims of abuse or other criminal activity, and their commitment is reflected in their ongoing compliance with State and local reporting laws. Commenters emphasize the importance of confidentiality in the care of adolescents, with commenters characterizing Title X providers as access points for youth autonomy. Commenters argue that, without assurances of confidentiality, young people would not seek family planning services. They contend that the proposed changes to confidentiality protections would hinder access to contraception and information for young people, both of which have contributed to lower instances of teen pregnancy.

Response: The Department agrees with commenters who stress that Title X providers must continue to comply with laws concerning patient confidentiality, including those specifically pertaining to the confidentiality for minors with respect to Title X services. For this reason, the Department does not change the current regulatory provision that requires that all information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and

[89] *See* 42 U.S.C. 300–300a–6; HHS Appropriations Act 2019, Public Law 115–245, Div. B, secs. 207–208 132 Stat. at 3090.

not be disclosed without the individual's documented consent, except as necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. The Department also does not change the further specification in the rule that, in any other case, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. The rule will, thus, continue to protect the confidentiality of patient information subject to these well-established exceptions and limitations. The only change is to clarify that the concerns for ''appropriate safeguards for confidentiality'' may not be used as a rationale for noncompliance with State or local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar criminal activity.

The Department believes the final rule is consistent with standard health care confidentiality practices, in which providers already have conversations with their patients, document those discussions in patient records, and comply with State and local reporting requirements, while otherwise maintaining the confidentiality of that information. Although the Department understands the challenge of balancing protection for victims, complying with State reporting laws, and maintaining trust in the patient-provider relationship, the Department's annual appropriations law requires that Title X projects comply with such State reporting requirements. Moreover, the Department believes that Title X programs can best serve minors and other vulnerable populations by ensuring Title X providers have a plan for reporting abuse as required by State and local reporting laws. Title X projects and participating entities can comply with these reporting requirements and document the measures taken to comply, much as health care providers do in other contexts, without infringing in any way on patient confidentiality.

H. Standards of Compliance With Prohibition on Abortion (42 CFR 59.13)

Summary of changes: The proposed rule would add § 59.13, which would specify that ''[a] project may not receive funds under this subpart unless it provides assurance satisfactory to the Secretary that, as a Title X grantee, it does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements in §§ 59.14 through 59.16. A project supported under this subpart must comply with such requirements at all times during the project period.''

The Department finalizes this definition with changes in response to comments that emphasize the grantee's responsibility to provide satisfactory assurance to the Secretary that the project complies with the statutory and regulatory Title X requirements.

Comments: One commenter states that the definitions of ''grantee'' and ''project'' are unclear and create confusion. Specifically, the commenter states that, under § 59.13, ''[a] project may not receive funds under this subpart unless it provides assurance satisfactory to the Secretary that, as a Title X grantee, it does not provide abortion and does not include abortion as a method of family planning.'' Project, however, is defined to ''mean a plan or sequence of activities that fulfills the requirements elaborated in a Title X funding announcement and may be comprised of, and implemented by a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area.'' The commenter contends that § 59.13 treats ''grantee'' and ''project'' interchangeably, and therefore causes confusion, as well as risking the interpretation that, under § 59.13, the grantee may not provide abortion or include abortion as a method of family planning both inside and outside the project. The commenter contends this ambiguity fails to give applicants a sufficient understanding of how the rule works, and what conditions apply to applicants for grants.

Commenters also assert that the regulations do not articulate how compliance should be demonstrated under § 59.13, and what documentary evidence would be necessary to provide this assurance.

Other commenters raise general concerns discussed elsewhere in this preamble.

Response: The Department agrees with the commenter that there is a lack of clarity with respect to the use of the terms ''grantee'' in § 59.2 and ''project'' in § 59.13. The Department intends the compliance standards in § 59.13 to apply to a grantee's activities within a Title X project, not to a grantee's activities outside of a project. The Department recognizes that an entity that serves as a Title X grantee may provide abortion or include abortion as a method of family planning separate from, independent of, and outside, the Title X project for which the grantee has been selected. Such an entity may still qualify for a Title X grant, so long as it meets each of the requirements in §§ 59.13 through 59.16 with respect to the project, including but not limited to the physical and financial separation, and ensures compliance with those requirements by its subrecipients with respect to the project. This recognition is consistent with *Rust* v. *Sullivan* [90] and the 1988 regulations.[91] The Department believes that the lack of clarity in the proposed rule was not due to the definition of ''grantee'' in § 59.2, but the use of the terms ''grantee'' and ''project'' in § 59.13.

The Department addresses this confusion by modifying a phrase and adding further clarity with regard to where responsibility for compliance lies.[92] Consequently, the Department finalizes § 59.13 to state: ''A project may not receive funds under this subpart unless the grantee provides assurance satisfactory to the Secretary that the project does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements in §§ 59.14 through 59.16. A project supported under this subpart must comply with such requirements at all times during the project period.'' The Department believes this change addresses the confusion raised by the commenter concerning how the definition of grantee applies in § 59.13.

The Department disagrees with commenters who contend the proposed rule at § 59.13 gives improper or unprecedented regulatory authority to the Department beyond the concern addressed above. Title X authorizes the Secretary to promulgate regulations governing grants and contracts issued in the program. 42 U.S.C. 300a–4. Thus, the Department is authorized, and in many cases required to, apply requirements both to primary grantees and to subrecipients of Title X funds. This includes the requirements set forth in section 1008.

[90] 500 U.S. 173.

[91] 42 CFR 59.1–59.12 (1988 ed.), 53 FR 2922 (Feb. 2, 1988).

[92] As discussed above, the Department believes the concern raised by the commenter does not require a change to the definitions of ''grantee'' and ''project'' in § 59.2, since they are clear, and not the subject of the commenter's concern.

The Department disagrees with commenters who assert that the regulations do not articulate how compliance should be demonstrated under § 59.13, and what documentary evidence would be necessary to provide this assurance. The plain text in proposed § 59.13 would require that the grantee provide representations of compliance with the section and each of the requirements in §§ 59.14 through 59.16, and be prepared to support the representations with documentary evidence of compliance if requested by the Department. Proposed § 59.17(b) similarly requires the establishment and documentation of certain protocols, plans and training related to knowledge of and compliance with certain State or local notification or reporting requirements. The grantee would provide a representation or assurance that it has adopted the required protocols and conducted/provided the required training. The types of documentary evidence that might be required could include (1) copies of the protocols or plans that have been adopted and implemented; (2) copies of the training materials; (3) training session sign in sheets; and (4) notations in patients' records as to reporting, notification, or in the case of minors, screening for abuse or victimization. To the extent that additional documentation is required by the Secretary at a later date, future guidance will be communicated to grantees.[93]

I. Requirements and Limitations With Respect to Post-Conception Activities (42 CFR 59.14)

Summary of changes: The proposed rule would add § 59.14, which would provide guidance to grantees regarding the requirements and limitations of the Title X program with respect to the post-conception activities of projects and clinics. Sections 59.5(a)(5) and 59.16(a) contain related provisions. Because many comments on these related sections overlap, some comments (and responses) in this section are also applicable to those sections as well.

Comments concerning the prohibition on providing or performing abortion as a method of family planning are addressed above in the discussion of the definition of ''family planning'' in § 59.2 and in the discussion of the prohibition on providing, promoting, referring for, or supporting abortion as a method of family planning in § 59.5(a)(5).

Comments concerning the rescission of the requirement in the 2000 regulations to provide abortion counseling, information, and referrals, and concerning nondirective pregnancy options counseling under this rule, are addressed above in the discussion of § 59.5(a).

Comments concerning the prohibition on referral for abortion as a method of family planning, on the promotion, or support of abortion as a method of family planning, and on taking affirmative action to assist a patient to secure an abortion, are considered here, and relate to § 59.14 as well as parts of §§ 59.5(a)(5) and 59.16(a).

The Department finalizes the language at § 59.14 with changes in response to public comments, as discussed below.

1. Prohibition on Referral for, and Encouragement, Promotion, Advocacy, Support, and Assistance of, Abortion as a Method of Family Planning (42 CFR 59.14(a), Inclusive of Pertinent Portions of §§ 59.5(a)(5), and 59.16(a))

Summary of changes: The first sentence of proposed § 59.14(a) would provide that ''[a] Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion.'' This sentence remains unchanged in the final rule. The remaining language in § 59.14(a) would permit doctors to provide a list of licensed, qualified, comprehensive primary health care providers (some of which may also provide abortion services) and guidance on circumstances when the list could be provided. The Department now finalizes language in the first sentence without change. In response to comments, the Department has updated the remaining language of § 59.14(a), regarding the list of comprehensive health service providers and has updated the examples listed at the end of § 59.14. Further discussion of these changes regarding the list is included in the subsection below, entitled ''Information About Prenatal Care, Use of Permitted Information To Refer For Abortion, and Examples (42 CFR 59.14(b), (c), and (e)).'' A further discussion of this prohibition is also included in the discussion of § 59.16, which contains a related provision.

Comments: Many commenters strongly support the proposed language to prohibit Title X projects from referring for abortion as a method of family planning and from promoting, supporting, encouraging, advocating for, or assisting abortion as a method of family planning. They contend these prohibitions are consistent with Congressional intent for Title X, including in section 1008 of the PHS Act. Some commenters note that, in *Rust,* 500 U.S. at 17892, the Supreme Court upheld a prohibition on abortion referrals in the 1988 regulations as being both constitutionally valid and a permissible implementation of the statutory restrictions on the program. Another commenter states that the government is permitted to direct how Title X funds are spent, consistent with the Title X statute, and that this sustains the prohibition on referrals. The commenter contends the proposed rule would ensure not only that program funds are not used to directly provide abortions, but also that program funds do not support loopholes by which some providers abuse the system to refer for abortion as a method of family planning. Another commenter supports the proposed rule because it will be consistent with a number of State laws that prohibit Title X providers from referring for abortions.

Other commenters oppose the prohibition on abortion referrals. A significant number of commenters call the prohibition a gag rule, arguing it restricts providers from speaking freely with their patients about every health concern they may have. They state that this prohibition violates ethical standards and undermines the patient-provider relationship, noting that a health care provider should not fail to provide certain services, namely those associated with abortion, because of private religious beliefs. Some commenters also contend the proposed changes disregard the consciences of providers who support ensuring patient access to information related to abortion and abortion-related services, including providing abortion referrals. And some commenters state that the abortion referral prohibitions in the proposed rule regulate activities outside the Title X program and are, therefore, illegal.

A commenter supporting the proposed rule disputes the characterization of the prohibition on abortion referrals and promotion as a gag rule. The commenter contends the language merely implements what the law already requires and does not prevent physicians or APPs from providing nondirective counseling as long as it is done in a manner consistent with the Title X statute. In addition, the commenter notes that abortion referral prohibitions do not prevent a doctor from making medical determinations on behalf of a patient that require services

[93] Grantees are already required to affirm that neither they nor any of their subrecipients provide abortion as a method of family planning. At the present time, the Department contemplates a narrow compliance requirement where the grantee assures the Department of compliance and provides adequate representations to bolster that assurance, such as those discussed above.

outside of the scope of the Title X program.

Response: Having examined its past rules governing the Title X program, the public comments on this issue, and the Department's interpretations of section 1008's prohibition on funding Title X programs ''where abortion is a method of family planning,'' the Department concludes that the requirement in the 2000 regulations for abortion referral is inconsistent with the Department's current interpretation of section 1008.[94] The language of Section 1008 goes beyond merely prohibiting the funding of abortion (which is addressed in the Title X appropriation provision), or of projects that perform abortion. The Title X statute prohibits spending Title X funds on programs where abortion is treated as a method of family planning. This prohibition impacts Title X projects in a variety of ways. If a Title X project refers for, encourages, promotes, advocates, supports, or assists with, abortion as a method of family planning, it is a program ''where abortion is a method of family planning'' and the Title X statute prohibits Title X funding for that project. For this reason, the Department agrees with commenters who support the language prohibiting such activities in the proposed rule as legally permissible and appropriate.

The Supreme Court has already recognized the reasonableness of this interpretation. In *Rust,* the Supreme Court upheld the provisions in the 1988 regulations that a Title X project may not ''provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning,'' provisions implementing that prohibition, and provisions stating a Title X project may not ''encourage, promote, or advocate abortion as a method of family planning'' or ''assist women to obtain abortions.'' *See* 53 FR 2923–2924; *Rust,* 500 U.S. at 179–80. The Supreme Court held that ''[t]he broad language of Title X plainly allows the Secretary's construction of the statute'' to prohibit abortion referral, counseling, and advocacy, and the Secretary ''amply justified his changed interpretation.'' *Rust,* 500 U.S. at 184–87. The Court further concluded ''[t]here is no question but that the statutory prohibition contained in § 1008 is constitutional,'' because Congress ''may 'make a value judgment favoring childbirth over abortion, and . . . implement that judgment by the allocation of public funds.' '' Id. at 192 (internal citations omitted; ellipses in original). The court explained that the challenged provisions of the 1988 regulations were also consistent with the First Amendment:

> The challenged regulations implement the statutory prohibition by prohibiting counseling, referral, and the provision of information regarding abortion as a method of family planning. They are designed to ensure that the limits of the federal program are observed. The Title X program is designed not for prenatal care, but to encourage family planning. A doctor who wished to offer prenatal care to a project patient who became pregnant could properly be prohibited from doing so because such service is outside the scope of the federally funded program. The regulations prohibiting abortion counseling and referral are of the same ilk. . . . This is not a case of the Government 'suppressing a dangerous idea,' but of a prohibition on a project grantee or its employees from engaging in activities outside of the project's scope.

Id. at 193–94.

The Department disagrees with the view of some commenters that the prohibitions on referral for, encouragement of, promotion of, advocacy for, support of, or assistance with, abortion as a method of family planning regulate non-Title X activities. The Department intends these prohibitions to apply only to the Title X project. The Supreme Court, in *Rust* rejected a First Amendment claim in which the challengers contended that similar regulations apply outside the Title X project, stating that ''[t]he Secretary's regulations do not force the Title X grantee to give up abortion-related speech; they merely require that the grantee keep such activities separate and distinct from Title X activities. . . . The regulations govern the scope of the Title X project's activities, and leave the grantee unfettered in its other activities.'' *Rust,* 500 U.S. at 196. Furthermore, the Court stated that an entity that receives Title X funds ''can continue to perform abortions, provide abortion-related services, and engage in abortion advocacy; it simply is required to conduct those activities through programs that are separate and independent from the project that receives Title X funds.'' *Id.*

The Department also disagrees with commenters who contend that prohibiting referring for, promoting, supporting, encouraging, advocating for, or taking any other affirmative action to assist a patient to secure, abortion as a method of family planning in Title X projects violates the Church Amendment rights of Title X projects or their employees. Although paragraph (c)(1) of the Church Amendments protects personnel on the basis that they ''performed or assisted in the performance of a lawful . . . abortion,''[95] those are not inconsistent with the clear statutory prohibition that funds may not be provided to Title X projects where abortion is a method of family planning. Projects can comply with this prohibition on the use of Title X funds without discriminating against personnel in a way that violates the Church Amendments.

The Department, thus, finalizes the first sentence of § 59.14(a).

2. Information About Prenatal Care, Use of Permitted Information To Refer for Abortion, and Examples (42 CFR 59.14(b)(1), (c), and (e))

Summary of changes: The proposed rule would provide in § 59.14(b) that, once a Title X client is diagnosed as pregnant, she must be referred for appropriate prenatal and/or social services. The proposed rule also would have required that the project provide any information necessary to protect her health and the health of the unborn child until the referral appointment is kept, including referral for emergency medical services when appropriate. In § 59.14(c), the proposed rule would have acknowledged the duty of a physician to promote patient safety in allowing a doctor to provide a list, if asked, of licensed, qualified, comprehensive health service providers, some of which may provide abortion in addition to comprehensive prenatal care. In paragraph (e), the Department would set out several examples to illustrate the application of the requirements of paragraphs (a) through (d).

The Department finalizes § 59.14(b)(1) with changes, including to permit the provision of a single list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) to pregnant clients. In addition, the final rule requires referral for prenatal care since such care is medically necessary to maintain or improve the health of both the mother and the unborn baby. The Department simplifies and clarifies the description of pregnancy health information in this final rule to read ''[i]nformation about maintaining the health of the mother and unborn child during pregnancy.''

The Department also finalizes provisions addressing the permissive nature of nondirective pregnancy counseling and the provision of information about pregnancy health.

[94] As discussed *supra* at I(A)(2)(c) Nondirective Pregnancy Counseling Permitted, Not Required and elsewhere in this preamble, such a requirement also raises issues under the Church, Coats-Snowe, and Weldon Amendments.

[95] 42 U.S.C. 300a–7.

The Department is simplifying this language and separating the requirements into enumerated subparagraphs of paragraph (b)(1) for clarity. The final rule, thus, specifies that referrals for prenatal care are required, because of its medical necessity due to pregnancy. Further, the Title X provider may also choose, but is not required to, provide nondirective pregnancy counseling, referrals to social services or adoption agencies, and information consistent with Section 1008 and appropriate post-conception activities under Title X regulation.

As discussed below, the Department also finalizes, as proposed, the final sentence in proposed paragraph (b) concerning cases that require emergency care as paragraph (b)(2).

The Department finalizes § 59.14(c) with changes in response to comments, including the consolidation of the two lists of comprehensive health care providers (from paragraphs (a) and (c) of the proposed rule) into one list and the addition of the requirement that the list and project staff not identify which providers on the list, if any, perform abortion.

The Department finalizes § 59.14(e), which sets forth examples illustrating the rules described in paragraphs (a) through (d), with changes consistent with the changes to those subsections.

Comments: Many commenters oppose the list of providers that may be shared with pregnant patients who request abortion. Commenters believe the list lacks necessary detail, may be difficult to understand for some patients, and difficult to implement for some providers because of the lack of comprehensive service providers who also provide abortion in their community.

Other commenters oppose the fact that the list may include some health providers that perform abortions, contending that Title X projects should not provide women seeking abortion with any list of providers that perform abortion. They contend providing such a list, or any information a woman may use to obtain an abortion, would violate section 1008 as it would make the project one ''where abortion is a method of family planning.'' Such commenters also contend providing such a list would constitute a referral for abortion. They point to the proposed rule, published by the HHS Office for Civil Rights in January 2018 to implement conscience laws such as the Weldon Amendment, defining referral as providing information that could provide assistance in obtaining a particular health care service. *See* 83 FR 3880, 3924 (Jan. 26, 2018).[96]

Several commenters contend that rule's description of two lists—one that may include abortion providers to be given to pregnant patients who want an abortion (described in § 59.14(a) and (c)), and another (described at the end of § 59.14(a)) that does not include abortion providers and that would be given to all other pregnant patients—is confusing and cumbersome for both the patient and the provider.

Other commenters object to the requirement that only doctors are permitted to give the list of providers to a woman seeking abortion described in § 59.14(a) and (c).

Some commenters assert that requiring referrals for pregnant patients to obtain prenatal and/or social services, regardless of the patient's wishes, violates the Congressional requirement that all Title X counseling be nondirective.

Many commenters present objections to the examples set forth in subsection (e) consistent with their objections to the requirements of subsection (a) that those examples illustrate.

Response: The Department agrees that it is appropriate to implement section 1008 to prohibit referrals for, and encouragement, promotion, advocacy, support, and assistance of abortion. The Department also agrees that, while nondirective pregnancy counseling is permissible in Title X projects by physicians or APPs, even if nondirective abortion counseling is provided among other options (so long as the counseling falls within parameters of the Title X statute and this regulation), abortion referral is inconsistent with the prohibition against funding Title X projects where abortion is a method of family planning.

The Department's approach to counseling is somewhat different than in the 1988 regulations, which, in addition to prohibiting abortion referrals, also prohibited ''counseling concerning the use of abortion as a method of family planning.'' In subsequent years, Congress has indicated that nondirective postconception counseling would be permissible, without requiring that any such counseling occur. It has done so through appropriations law provisions requiring that any pregnancy counseling offered in Title X projects be nondirective.[97] The Department believes these enactments make it appropriate for the Department to allow nondirective pregnancy counseling in Title X projects by physicians or APPs, even if the counseling includes nondirective counseling on abortion. Although Congress did not require projects to offer pregnancy counseling, a permissible interpretation of the statutory provision requiring that any such counseling be nondirective is that abortion may be discussed in a nondirective way. The Department believes that it would also be a permissible interpretation to conclude that, even without discussion of abortion, other nondirective counseling should be presented to the pregnant woman. In the absence of more specific direction from Congress in the nondirective counseling provision, the Department concludes that it is permissible to interpret the various statutory requirements for Title X so as to permit projects to provide nondirective pregnancy counseling, even if it involves counseling on abortion, as long as that counseling is truly nondirective.

As clarified by the direction given by Congress, nondirective counseling is consistent with the provision as analyzed in *Rust.* The 1988 regulations upheld in *Rust* stated a Title X project may not, among other things, ''provide counseling concerning the use of abortion as a method of family planning,'' ''provide referral for abortion as a method of family planning,'' ''encourage, promote or advocate abortion as a method of family planning,'' or ''use prenatal, social service or emergency medical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning, such as by weighing the list of referrals in favor of health care providers which perform abortions, by including on the list of referral providers health care providers whose principal business is the provision of abortions, by excluding available providers who do not provide abortions, or by 'steering' clients to providers who offer abortion as a method of family planning.'' *Rust,* 500 U.S. at 179–80 (*citing* 42 CFR 59.8(a)(1)–(3) (ed. 1988)). In upholding those provisions, the Supreme Court added that the Department may also prohibit ''abortion-related speech'' and ''abortion advocacy'' in a Title X project. *Rust,* 500 U.S. at 175. The language of this final rule, which at §§ 59.14(a) and 59.16(a) similarly prohibits a Title X project from referring for, promoting, supporting, encouraging, advocating for, or taking any other affirmative action to assist a patient to secure, abortion as a method

[96] That proposed rule has not yet been finalized.

[97] *See* Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, sec. 104, 110 Stat. 1321; HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. 3070.

of family planning, is consistent with the provisions of the 1988 regulations that the Supreme Court upheld in *Rust.* Thus, the Supreme Court's conclusions upholding these provisions of the 1988 regulations would be equally applicable to this final rule and the permissions surrounding nondirective pregnancy counseling.

The Department has seriously considered the many comments offered regarding the two lists referenced in proposed § 59.14(a) and (c): One list required for pregnant clients generally, and another list permitted in the more specific circumstance where pregnant clients have decided to seek an abortion and request an abortion referral. The Department agrees that the proposal for two lists to be provided in two different and specific circumstances was potentially confusing and/or burdensome for projects which might be confused or unclear about how to develop and implement the lists. The proposed rule's duplicative description (in both paragraphs (a) and (c)) of the more specific list allowed when a client requests abortion may also have been confusing. And although the proposed rule attempted to describe, in more detail, how a project would respond to requests for abortion or abortion referrals, the Department concludes that description was also potentially confusing and is unnecessary in the final rule.

The Department is finalizing § 59.14(b)(1)(ii) to allow Title X providers to give a single list of providers to any pregnant woman. This list will contain licensed, qualified, comprehensive primary health care providers (including providers of prenatal care). At § 59.14(c), the Department consolidates and finalizes the description and requirements applicable to such list. The Department permits, but does not require, some providers on the list of comprehensive primary health care providers (including providers of prenatal care) to be providers that also provide abortion. The Department believes this will enable some projects to create a single list of comprehensive primary health care providers (including providers of prenatal care). For example, some service sites might find that the main provider of comprehensive primary or prenatal health care services is a hospital that also performs some abortions. At the same time, projects cannot create or distribute a list in which every provider (or a majority) on the list provides abortion. Projects, however, may compile their list so that no providers of abortion are on the list.

Because referrals for abortion as a method of family planning are prohibited, the list of comprehensive primary health care providers (including providers of prenatal care) that Title X projects and providers may provide to pregnant clients (and which may include abortion providers) cannot be used to indirectly refer for abortion or to identify abortion providers to a client. Thus, in the circumstance where a pregnant woman asks for an abortion or an abortion referral for family planning purposes, the project's response would be to say it does not refer for abortions, and then to offer her, if she desires, a list of comprehensive primary health care providers (including providers of prenatal care); that list could include (but not identify) such providers that also perform abortions.

The Department believes these limitations on the list of comprehensive primary health care providers (including providers of prenatal care), as well as the context in which the list would be provided, prevents distribution of that list from violating section 1008, even if some providers on the list also provide abortions. There are many potential reasons or purposes for a Title X provider to provide the list to a pregnant patient. If provision of the list is for a referral purpose, it must be for a permissible purpose, such as to refer the patient for prenatal care or for care of pre-existing maternal health conditions, not for the purpose of referring for abortion as a method of family planning. The final rule prohibits the list and project staff from identifying which, if any, providers on the list provide abortions. The Department, therefore, disagrees with some commenters who contend that including any abortion providers on a list of comprehensive primary and/or prenatal health care providers would render the project one ''where abortion is a method of family planning.''

In response to comments, the Department has decided to eliminate the requirement that a list provided specifically to women seeking abortion referrals be provided only by a doctor. Some commenters object to this requirement and note that the proposed rule did not require the list of prenatal care referrals, which was to be provided to all pregnant women, to be provided only by a doctor. Upon consideration of these comments, the Department has decided not to finalize any restriction on which personnel may provide the list to a pregnant patient. Any member of the Title X staff may provide the list, but only physicians and APPs may provide any nondirective pregnancy counseling.

In light of section 1008 and federal conscience laws, the Department has concluded it will not require Title X projects to offer nondirective counseling or information about abortion. The Department similarly will not require projects to offer nondirective pregnancy counseling on other subjects if they choose not to do so. Congress did not require that projects offer pregnancy counseling, but only that such counseling be nondirective, when/if offered. The Department concludes that the final rule should take a similar approach. Accordingly, this rule does not require a Title X project to offer abortion-related pregnancy counseling (or pregnancy counseling at all). When a project chooses to offer such pregnancy counseling, it must be nondirective. The clinic may offer referral services except that, given the statutory parameters set forth in Section 1008, a project is not permitted to provide referrals for abortion as a method of family planning.[98] As noted above, with respect to § 59.5(a)(5), this final rule rescinds the requirement of pregnancy options counseling from the 2000 regulations. This final rule neither requires nor prohibits pregnancy counseling (although pursuant to Congressional mandate, if such counseling occurs, it must be nondirective). Consistent with federal law (including the requirements of this final rule), Title X projects and providers must comply with all applicable laws concerning the practice of medicine and the offering of medical advice, as they may apply to the Title X project or provider that provides pregnant clients with nondirective pregnancy counseling, a list of comprehensive primary and prenatal health care providers, prenatal care referrals, assistance with setting up referral appointments, or information about pregnancy health.

Some commenters contend that providing prenatal care referrals violates Congress's requirement that pregnancy counseling be nondirective. The Department responds to this comment above in its discussion of referrals for prenatal care and adoption in § 59.2. Prenatal care is medically necessary for any patient who is pregnant, so referrals for such care do not render counseling directive. Moreover, the Department notes that low income women are more likely to deliver low birthweight babies

[98] Projects may permit each Title X clinic to make the decision whether it will provide each aspect of permissible counseling. The Department notes, however, that clinics, providers, and staff cannot be required to counsel on abortion if, for example, such activity would be contrary to their religious beliefs or moral convictions.

and to deliver before term, and less likely to access adequate prenatal care services. Yet prenatal care is one of 14 mandatory categories of Medicaid services and is deemed medically necessary for pregnant women. Because prenatal care is essential in order to optimize the health of the mother and unborn child, and to help ameliorate the current health inequality as it relates to low income women,[99] referring low income pregnant women for prenatal care is of increased importance.[100] Therefore, the Department adds additional clarity regarding referrals for prenatal care in an example in § 59.15(e)(1). The Department continues to believe that Title X projects are well situated to provide such referrals.

The Department does not, however, agree with the commenter who proposes that Title X providers are responsible for prenatal care. While the Department agrees that prenatal care is important to maternal and infant outcomes, and encourages Title X providers to provide comprehensive health care services onsite or through robust referral networks, the provision of postconception and pregnancy services (as distinct from information and referrals for them) are outside the scope of Title X.

Accordingly, the Department is finalizing this section as discussed to simplify and clarify the approach set forth in the proposed rule. Consequently, § 59.14(a) is finalized to prohibit Title X projects from referring for abortion, which includes ''any affirmative action to assist a patient to secure such an abortion.'' Section 59.14(b)(1) is also finalized to only require Title X projects to refer pregnant clients to a ''health care provider for medically necessary prenatal health care.'' Subsection (b)(1) also establishes that the Title X provider may also provide certain specified counseling and/or information to the pregnant woman. Finally, subsection (b)(2) establishes that, in cases requiring emergency care, referral is required ''to an appropriate provider of medical services needed to address the emergency.'' [101] Section 59.14(c) is finalized to establish that a Title X project may not use lists, referrals, or counseling ''as an indirect means of encouraging or promoting abortion as a method of family planning.'' Subsection (c) further establishes that while the list may include some providers who provide abortion services, ''[n]either the list nor project staff may identify which providers on the list perform abortion.''

The Department is finalizing the changes described above to reduce confusion, facilitate implementation of the rule, provide pregnant clients with counseling and information for prenatal care and information to promote the health of the mother and unborn child, and implement section 1008 to ensure Title X does not fund projects where abortion is a method of family planning. The Department also finalizes the examples in paragraph (e), with changes corresponding to the changes made in paragraphs (a) through (d).

3. Emergency Care and Medically Necessary Information (42 CFR 59.14(b)(2) and (d))

Summary of changes: In the last sentence of § 59.14(b), the proposed rule would require that, ''[i]n cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of emergency medical services.'' The Department finalizes § 59.14(b)(2), in response to comments discussed below, by replacing ''an appropriate provider of emergency medical services'' with ''an appropriate provider of medical services needed to address the emergency.''

At § 59.14(d), the proposed rule would provide: ''Provision of medically necessary information. Nothing in this subpart shall be construed as prohibiting the provision of information to a project client that is medically necessary to assess the risks and benefits of different methods of contraception in the course of selecting a method, provided that the provision of such information does not otherwise promote abortion as a method of family planning.'' The Department finalizes § 59.14(d) without change.

Comments: Some commenters object that the proposed rulemaking does not allow for medically necessary, but non-emergency, referrals for abortion. These commenters state that when maternal and child health outcomes will be compromised if a pregnancy is continued, or if appropriate treatment and services are delayed, referral for abortion is needed.

Several commenters express concern that the proposed language would allow providers to refer patients who need emergency care only to an emergency room, which may not be the best place for the patient. They assert that this will increase unnecessary emergency room use. Commenters ask the Department to clarify in the rulemaking that providers be allowed to refer the pregnant woman to the provider that is clinically appropriate for the patient.

Several other commenters request that the Department clarify the language in the proposed rulemaking regarding women who experience ectopic pregnancies and other life-threatening conditions related to pregnancy. They contend that the exception for ''danger of death'' should be included in the discussions of the Hyde Amendment. They contend this would assure that Title X providers have accurate information to be compliant and consistent among federal agencies.

Response: The Department disagrees with commenters contending that restrictions in the rule on referral and directive counseling affect situations concerning emergency or medically necessary care. Section 1008 prohibits funding for Title X projects where abortion is a method of family planning, and the final rule's restrictions on referral, promotion, or encouragement of abortion are similarly limited to abortion as a method of family planning. Referral for abortion because of an emergency medical situation does not fall into restrictions concerning abortion as a method of family planning. Paragraph (b)(1) of § 59.5 of the final rule makes clear that Title X grantees and subrecipients not only may, but must, provide for ''referral to other medical facilities when medically necessary.'' *See also* § 59.5(b)(8).[102]

The Department appreciates commenters who suggest that the final sentence in proposed § 59.14(b) limits referral to emergency rooms. The Department agrees with a commenter who stated that a hospital emergency room may not always be the most appropriate referral location and that the referral should be commensurate with the medical need. Because the text of the proposed rule would require only referral to ''an appropriate provider of emergency medical services,'' the Department finalizes this language with clarification to avoid confusion and to emphasize, ''[i]n cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to

[99] Tanya Nagahawatte and Robert L. Goldenberg, *Poverty, Maternal Health, and Adverse Pregnancy Outcomes,* 1136 Ann. N.Y. Acad. Sci. 80, 81 (2008), *https://www.ncbi.nlm.nih.gov/pubmed/17954684.*

[100] Rita Hamad and David H. Rehkopf, Poverty, Pregnancy, and Birth Outcomes: Earned Income Tax Credit, 29(5) Paediatr Perinat Epidemiol 444–452, Jul. 24, 2015. PMCID: PMC4536129.

[101] This sentence in § 59.14(b) is addressed in the immediately below section.

[102] As noted above, Title X projects and service providers must ensure that they do not, under the cover and pretext of providing such abortion referral, actually refer for abortion as a method of family planning. This is an area in which Title X projects can expect OPA monitoring and oversight, and should maintain appropriate records to support such referrals.

address the emergency.'' This language is intended to emphasize that it does not require that such referral be to an emergency room.

It is also not the intent of the regulatory provisions at § 59.14(b)(2) or § 59.5(b)(1) to restrict the ability of health professionals to communicate to a patient any information they discover in the course of physical examination (or otherwise) about her medical condition, such as an extant condition that might make her pregnancy high risk; to communicate an assessment of the urgency of the need for treatment; or to ensure that a patient is referred to the appropriate specialist for treatment of the condition, consistent with the exercise of his or her professional judgment and the parameters of the Title X program. The restrictions in these provisions solely concern abortion as a method of family planning. For this reason, the Department disagrees that these provisions of the final rule will increase medical liability, or will prohibit Title X projects from providing the factual information necessary to assess risks of a particular family planning or contraceptive method as set out in the patient package inserts.

As noted, at § 59.14(c), the final rule will also provide that a Title X project may not use emergency medical or other referrals as an indirect means of encouraging or promoting abortion as a method of family planning.

J. Maintenance of Physical and Financial Separation (42 CFR 59.15)

The proposed rule, at § 59.15, would require physical and financial separation of a Title X project or facility from prohibited activities (*e.g.,* abortion as a method of family planning).

The Department finalizes this section without change. The Department finalizes the compliance date for this section, as set forth in § 59.19, with changes in response to public comments, as discussed below.

Comments: Many commenters express support for the proposed financial and physical separation provisions and the Department's efforts to enforce the restrictions. These commenters agree that the proposed separation provisions will ensure statutory compliance with section 1008, eliminate potential confusion, and reduce the use of Title X funds for non-Title X services. One commenter adds that maintaining separate funds is a common requirement for federal grants and contracts. Another commenter states that, as upheld in *Rust* v. *Sullivan,* the Secretary is entitled to interpret Title X to include ''separate facilities.'' Several commenters point out that the proposed separation amendments are consistent with numerous State laws.

Many other commenters contend that the proposed financial and physical separation requirements and reduced flexibility of funds are illegal, not intended by Congress, burdensome, and unworkable. To begin, commenters claim that the Department fails to adequately justify why the change is necessary and argue that concerns about fungibility or possible co-mingling of funds are flawed. They assert that Title X already prohibits clinics from using federal funds to provide abortions and requires that funds used for abortion be kept separate, and that regular, extensive, and comprehensive audits currently are already used to enforce the existing rule. They contend that the 2000 regulations have successfully ensured separation compliance and that no additional measures are needed. They also contend that improving public education efforts so the public understands Title X funds cannot be used for abortion, would make physical separation unnecessary. These commenters urge the Department to withdraw the new separation requirement, or at a minimum, to provide clearer justifications for the requirement.

Some commenters focus on the possible burden and workability of the rule. They contend that the Department lacks evidence that the rules are feasible, particularly because the separation requirements in the 1988 regulations, which were nearly identical to the proposed rule here, were never fully implemented. They assert that the Department neglected to do adequate research and analysis of how the proposed changes would interact with various State laws, including laws that govern medical licensure and scope of practice. Some commenters state that a Department notice (Provision of Abortion-Related Services in Family Planning Projects, 65 FR 41281, 41282 (July 3, 2000)) allows Title X service sites to use common waiting rooms, staff, filing systems, and other resources and argue that changes to this approach would impair the family planning network by constraining certain providers' ability to participate in the Title X program. They state, for example, that many Title X grantees are hospitals that must be able to perform abortions in emergency situations and would not be able to afford separate infrastructure. Other commenters contend that the financial separation provisions would increase the cost of medical supplies and reduce grantees' ability to make cost-effective bulk purchases. Some commenters contend that 60 days from the date the final rule is published is insufficient time to accomplish the requirement of separate electronic health records. One commenter urges the Department to consult with a diverse group of Title X providers to calculate the monetary and time costs to comply with the proposed changes.

Some commenters contend that the rule will harm patient care. They state that, for women seeking both Title X services and abortion, the rule would require two separate visits to separate facilities because of effects of the restrictions on same-day post-abortion contraception. They claim that the need for two separate visits would create unnecessary costs and obstacles to care. Other commenters express concern that the new provisions would exacerbate health inequalities in terms of sexually transmitted diseases (STDs) among low income people affected by the loss of Title X providers. Some commenters state that the separation provisions undermine the objectives of integrated care and health systems. Similarly, many commenters argue that the requirement for separate electronic medical records (EHR) contradicts the principles of integrated, patient-centered medical care. They contend the financial separation requirement could lead to instances of missing or incomplete patient data and increased costs, as the same patient must have two separate medical records—one for Title X services and another for abortion services.

Some commenters raise other objections. One commenter, for example, expresses concern that the mandated physical separation would reinforce the notion that abortion is not a normal and legal part of health care. One commenter states that if the separation provisions force clinics that perform abortions to close, it would impede training for residents in obstetrics and gynecology. Another commenter expresses concern that requiring physical separation serves to highlight locations where abortion services are provided, which may increase the risk of those locations being the target of violent crime or protest. Several commenters object to the proposed signage requirements. Many other commenters object to the rule because, in their view, it gives the Department unrestricted authority to determine how to apply the separation requirements, while leaving Title X programs with insufficient guidance.

Finally, some commenters argue that mere physical and financial separation is not enough to ensure program integrity. They recommend Title X

clinics have distinctive names from clinics that offer abortions, distinct organizational entities, organizational headquarters, or unique signage and labeling on all Title X materials and service sites.

Response: The Department agrees with the commenters who support the rule and the Department's legal authority to require physical and financial separation. The rule is nearly identical to the policy set forth in the 1988 regulations, which was upheld by the Supreme Court in *Rust* v. *Sullivan.* 500 U.S. 173. After having reconsidered this issue, the Department's interpretation of section 1008 in the 1988 and 2000 regulations, and the public comments, the Department reaffirms its conclusions and its approach in the 1988 regulations with respect to physical and financial separation, as set forth in the proposed rule. The Department finds that the approach outlined in the proposed rule is in line with the Congressional mandate to separate Title X funds from those where abortion is a method of family planning. The Department finalizes that provision, with some changes discussed below.

In the 1988 regulations, the Department noted that it was requiring physical and financial separation because it found the regulations inadequate without that requirement, stating that the Department found, ''as a matter of experience with Title X, its responsibility to administer the program as provided by Congress, and its general administrative discretion, that the provisions of the current guidelines do not faithfully or effectively maintain the prohibition contained in section 1008.'' 53 FR at 2923. The 1988 regulations had several key features to address this deficiency and required compliance with the statutory prohibition. Among those, the regulations required grantees to separate their Title X project—physically and financially—from any abortion activities.

Those regulations were upheld on both statutory and constitutional grounds in *Rust.* 500 U.S. 173. The Supreme Court first rejected the claim that the regulations violated the Administrative Procedure Act. The Court concluded that—although the language of section 1008 did not directly prescribe physical and financial separation—the ''broad language of Title X plainly allows the Secretary's construction of the statute.'' *Id.* at 184. The Court declined to view the regulations skeptically merely because the agency had changed its view and reaffirmed the legal principle that ''[a]n agency is not required to 'establish rules of conduct to last forever,' but rather 'must be given ample latitude to 'adapt [its] rules and policies to the demands of changing circumstances.' '' *Id.* at 186–87 (internal citations omitted). The Court held the portions of the regulations mandating separate facilities, personnel, and records were ''based on a permissible construction of the statute and are not inconsistent with congressional intent.'' *Id.* at 188. On the contrary, the Court noted, ''if one thing is clear from the legislative history, it is that Congress intended that Title X funds be kept separate and distinct from abortion-related activities. . . Certainly, the Secretary's interpretation of the statute that separate facilities are necessary, especially in light of the express prohibition of [section] 1008, cannot be judged unreasonable.'' *Id.* at 190. Accordingly, the Court ''defer[red] to the Secretary's reasoned determination that the program integrity requirements are necessary to implement the prohibition.'' *Id.*

The Court similarly rejected constitutional challenges to the regulations. As an initial matter, it upheld the statutory limitation of Title X funds to programs where abortion is not a method of family planning, concluding that ''[t]here is no question but that the statutory prohibition contained in [section] 1008 is constitutional'' because Congress ''may 'make a value judgment favoring childbirth over abortion and . . . implement that judgment by the allocation of public funds.' '' 500 U.S. at 192–93 (internal citations omitted; ellipsis in original). The Court explained that the requirement of physical and financial separation was also consistent with the First Amendment:

> By requiring that the Title X grantee engage in abortion-related activity separately from activity receiving federal funding, Congress has, consistent with our teachings . . . not denied it the right to engage in abortion related activities. Congress has merely refused to fund such activities out of public fisc, and the Secretary is simply requiring a certain degree of separation from the Title X project to ensure the integrity of the federally funded program.

Id. at 198. The Court held that the regulations did not violate any Fifth Amendment rights because the ''Government has no constitutional duty to subsidize an activity merely because the activity is constitutionally protected and [Congress] may validly choose to fund childbirth over abortion and 'implement that judgment by the allocation of public funds' for medical services relating to childbirth but not to those relating to abortion.'' *Id.* at 201 (internal quotations omitted). The Court, thus, held that the regulations ''are a permissible construction of Title X and do not violate either the First or Fifth Amendments to the Constitution.'' *Id.* at 203.

The Department carefully considered the issue of physical and financial separation in light of the statutory guidance of section 1008 and notes that it is similar to the 1988 regulations, which were upheld by the Supreme Court. The Department has reconsidered the 2000 regulations, which allowed the sharing of physical space so long as certain financial separation was maintained. The Department continues to hold with the 2000 regulations, to the degree it requires financial separation, that financial separation is a necessary condition to implementing section 1008, but it no longer believes financial separation is sufficient without physical separation. For the reasons discussed below, financial separation without physical separation does not sufficiently address the Congressional mandate that Title X funds be separate and distinct from abortion-related services.

The Department disagrees with commenters who contend it has not provided sufficient reasons or evidence to justify the physical and financial separation requirements. In *Rust,* the Supreme Court upheld imposing those requirements as a legitimate interpretation of the Congressional mandate in section 1008, and the Department continues to believe that the physical and financial separation requirements are in line with that mandate. 500 U.S. at 203. But the Department also believes that such separation would appropriately address certain concerns it has with the current arrangements in which physical separation is not required. First, under the current arrangement, it is often difficult for patients, or the public, to know when or where Title X services end and non-Title X services involving abortion begin. As the Department explained in the proposed rule, shared facilities create a risk of the intentional or unintentional use of Title X funds for impermissible purposes, the co-mingling of Title X funds, the appearance and perception that Title X funds being used in a given program may also be supporting that program's abortion activities, and the use of Title X funds to develop infrastructure that is used for the abortion activities of Title X clinics. Even with the strictest accounting and charging of expenses, a shared facility greatly increases the risk of confusion and the likelihood that a violation of the Title X prohibition will occur.

This concern is particularly acute in light of more recent evidence that abortions are increasingly performed at sites that focus primarily on contraceptive and family planning services—sites that could be recipients of Title X funds. A 2014 report from the Guttmacher Institute provides detail about the various types of facilities at which abortions are performed.[103] It notes that ''nonspecialized clinics''—*i.e.,* ''nonhospital sites in which fewer than half of patient visits are for abortion services,'' including physicians' offices—may provide 400 or more abortions per site per year.[104] The report notes that, ''[w]hile many of these [nonspecialized] clinics primarily serve contraceptive and family planning clients, about half provided 400 or more abortions per year.'' [105] It defines ''abortion clinics'' as ''nonhospital facilities in which half or more of patient visits are for abortion services, regardless of annual abortion caseload.'' [106] According to the Guttmacher Institute, nonspecialized clinics accounted for 24% of all abortions in 2008; [107] 31% in 2011; [108] and 36% in 2014.[109] In addition, nonspecialized clinics represented 26% of abortion providers in 2008; [110] 30% in 2011; [111] and 31% in 2014.[112] Further, despite a 3% drop in the total number of abortion facilities between 2011 and 2014, the number of abortion clinics dropped by 17%, while the number of nonspecialized clinics performing abortions remained stable.[113] The performance of abortions at nonspecialized clinics that also may provide Title X services increases the risk and potential both for confusion and for the co-mingling or misuse of Title X funds.

Together, these circumstances create a risk of intentional or unintentional misuse of Title X funds and have created public confusion over the scope of Title X services, about whether Title X projects provide abortion services, and about whether federal taxpayers fund abortion services provided by organizations that are grantees (or subrecipients) of Title X grants/funds. The Department believes that such potential co-mingling and confusion provides sufficient supporting evidence, in addition to the Department's rationale for physical and financial separation upheld in *Rust* (which the Department also adopts now), that the 2000 Regulations neither adequately reflect nor ensure compliance with the text and purpose of section 1008. It is generally the Department's view that, if it is difficult to distinguish Title X activities from non-Title X activities, then adequate physical separation has not been achieved.

As discussed above, the Department interprets section 1008 to require Title X project activities to be separate and distinct from prohibited activities (*e.g.,* abortion as a method of family planning). Thus, the Department finalizes the proposed text of § 59.15 so that, when a grantee or subrecipient conducts abortion activities that are not part of the Title X project, and would not be permissible if they were, the grantee must ensure that the Title X-supported project is separate and distinguishable from those other activities.

The Department disagrees with comments opposing the requirement of physical separation on the basis that other means exist to achieve same goals of the proposed rule while still allowing the Title X project and a program engaged in prohibited activities to occupy the same physical space. The Department considered other alternatives to physical separation. For example, it considered whether signs or brochures could be posted to indicate distinctions between the Title X project and Title X prohibited activities, or whether separate staff and examinations rooms within the same area in the facility could sufficiently delineate a separation between the Title X project and abortion-related services. The Department has determined, however, that a shared reception area with materials available on both Title X family planning services and abortion-related services would not resolve the confusion, but could allow it to continue. Signage is often not read, and the segregation of staff or staff responsibilities would not, in the Department's view, provide sufficient distinction to end confusion. Single facilities often have staff fulfilling distinct roles without making the program itself separate. Patients might not be aware of the distinction made between different examination rooms if the entrance and reception area is shared in common, especially in a smaller facility. The optics and practical operation of two distinct services within a single collocated space do not sufficiently create the separation Congress intended when it said Title X funds cannot be spent ''where'' abortion is a method of family planning. As in its 1988 regulations, the Department interprets section 1008 to require clear physical separation between Title X projects and places ''where'' abortion is offered as a method of family planning.

The Department agrees that educational efforts to help the general public understand the services provided by Title X as well as those not provided by Title X, would be beneficial and will be considered by the Department. The Department believes that public educational efforts could augment the requirement for physical separation and contribute to more accurate public perception. But such efforts do not negate the need for clear and understandable separation between Title X services and abortion services at the clinic level. Physical separation assists with statutory compliance, in addition to improving public perception, by ensuring that both intentional and unintentional comingling of resources, activities, and services do not take place in ways that are exacerbated when both services are housed in the same space.

The final rule seeks to reduce, and potentially eliminate, any confusion—actual or potential—as to the scope of services supported by Title X funds by requiring funded projects to maintain clear physical and financial program separation from programs that use abortion as a method of family planning. The Department believes the rule will create a clearer and more transparent system of separation and accountability, similar to that established by the 1988 regulations and affirmed in *Rust.* It will also help assure fidelity to the text and purpose of section 1008 and facilitate auditing and enforcement of program requirements. The rule does not, however, restrict the use of non-Title X funds outside the Title X program, nor does it impose restrictions on funds provided by other federal programs.

The Department disagrees with commenters who contend that, because the Department did not have sufficient

[103] Rachel K. Jones and Jenna Jerman, *Abortion incidence and service availability in the United States, 2014,* 49 Guttmacher Institute Perspectives on Sexual and Reproductive Health 17, 19 (2017), *https://www.guttmacher.org/journals/psrh/2017/01/abortion-incidence-and-service-availability-united-states-2014.*

[104] *Id.* at 19.

[105] *Id.* at 20.

[106] *Id.* at 19.

[107] Rachel K. Jones and Kathryn Kooistra, *Abortion incidence and access to services in the United States, 2008,* 43 Guttmacher Institute Perspectives on Sexual and Reproductive Health 41, 46 (2011), *https://www.guttmacher.org/sites/default/files/pdfs/pubs/psrh/full/4304111.pdf.*

[108] Rachel K. Jones and Jenna Jerman, *Abortion incidence and service availability in the United States, 2011,* 46 Guttmacher Institute Perspectives on Sexual and Reproductive Health 3, 6 (2014), *https://www.guttmacher.org/sites/default/files/article_files/abortion_incidence_in_the_united_states_2011.pdf.*

[109] *See* Jones 2017, supra at 20.

[110] *See* Jones 2011, supra at 46.

[111] *See* Jones 2014, supra at 6.

[112] *See* Jones 2017, supra at 20.

[113] *See* Jones 2017, supra at 20.

opportunity after several years of litigation to put the 1988 regulations into effect before a new administration chose not to implement them, the Department may not implement essentially the same rules now. When the Supreme Court upheld the 1988 regulations, the Court held it was legally permissible for the Department to put them into effect. Nothing in the Administrative Procedure Act precludes the Department from re-adopting regulatory provisions that it had previously adopted, successfully defended in court, and then rescinded.

Commenters contend that the Department should have conducted more research regarding State laws, and regulation implementation costs by interviewing Title X providers. However, the number or administrability of State laws cannot take precedence over the statutory requirements of the federal Title X grant program. Additionally, the large volume of responses submitted within the 60-day comment period verifies that this process was sufficient for organizational and State stakeholder responses, both of which the Department received and carefully considered.

With respect to the contention of some commenters that the physical and financial separation requirements will destabilize the network of Title X providers, the Department disagrees. The rule continues to allow organizations to receive Title X funds even if they also provide abortion as a method of family planning, as long as they comply with the physical and financial separation requirements. The rule also allows case-by-case determinations on whether physical separation is sufficiently achieved to take the unique circumstances of each program into consideration. As is true for all program requirements, the Department welcomes regular interaction with grantees and subrecipients, should they have questions. Project officers are available to help grantees successfully implement the Title X program in compliance with both the statute and the regulation. The Department encourages grantees to contact the program office with questions, discuss ways to comply with the physical separation requirement, and put a workable plan in place to meet the compliance deadline. Moreover, the Department will not require compliance with the physical separation requirements of § 59.15 until one year after this final rule is published in the **Federal Register**. This will give grantees and subrecipients time to make arrangements to comply with physical separation requirements if they choose to seek Title X funds (or to participate in a Title X project) and also offer abortions as a method of family planning. Other provisions of the rule encourage additional entities to apply for Title X grants and additional individuals and institutions to participate in the Title X program. If certain grantees and/or subrecipients choose not to continue in the Title X program because they elect not to comply with the physical separation requirements in § 59.15 in one year, the Department will be in a position to continue to fulfill the purpose of Title X by funding projects sponsored by entities that will comply with the physical separation requirement and provide a broad range of family planning methods and services to low income clients. In several locations, there are already competing applicants to serve the same region. The Department believes that, overall, the final rule will contribute to more clients being served, gaps in services being closed, and improved client care that better focuses on the family planning mission of the Title X program.

Commenters' insistence that requiring physical and financial separation would increase the cost for doing business only confirms the need for such separation. If the collocation of a Title X clinic with an abortion clinic permits the abortion clinic to achieve economies of scale, the Title X project (and, thus, Title X funds) would be supporting abortion as a method of family planning. Put differently, the abortion clinic would be benefiting from the presence of the Title X project in the same location. Moreover, it would be the participation of the Title X project in bulk purchases and other economies of scale that enables the abortion clinic to achieve economies of scale. Such an argument makes the case that comingling of funds between Title X and abortion services is difficult to avoid without a physical and financial separation between the two.

The final rule does not prevent a woman from seeking and obtaining an abortion. It simply draws a bright line between permissible services provided with Title X funds and prohibited abortion services. The Department, thus, disagrees with commenters who contend the rule should not be finalized because women might need to make separate visits if they seek both Title X services and abortions from a Title X provider. Congress chose to restrict the use of Title X funding in section 1008, and the Supreme Court held in *Rust* that the requirement of physical and financial separation is not an impermissible imposition on any Fifth Amendment right concerning abortion.

Moreover, for the reasons discussed above, the Department does not anticipate any loss of Title X providers that will exacerbate health inequalities or harm patient care. The Department anticipates that the rule, overall, will contribute to more clients being served and gaps in services being closed. In response to commenters who contend more time is needed than the proposed 60 days to implement aspects of § 59.15 other than physical separation, such as factors concerning separate signs and other forms of identification in paragraph (d), or factors concerning the requirement for separate electronic health care records in paragraph (c), which commenters say would require separate Electronic Health Record (EHR) systems, the Department disagrees. The Department notes that EHR systems would be considered part of the physical separation requirement. The Department found that approximately 80% of the 4,000 Title X sites were using an electronic practice management system in 2016, with about 70% using the more advanced EHR system.[114] For those with an EHR system, the implementation of a new site within the same system should take significantly less time than the one year provided in the final rule. In addition, depending upon the EHR system, it may not be necessary to acquire a new EHR license at all. While some EHR systems include integrated administrative or financial accounting systems, that is not the universal practice. Moreover, although some EHR systems can generate separate financial reports, as well as a variety of other useful information for the Title X program, current grantees should already maintain financial separation, so whether such separation is accomplished through an EHR system or another means, this rule should not impose additional burden on the provider.

Although the proposed rule does not identify these factors as such, factors (b)–(d) are factors that help determine whether there is physical separation (the degree of separation from facilities; existence of separate personnel, electronic or paper-based health records, and workstations; and the extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent). Accordingly, the 1-year compliance date applicable to physical separation will apply to them. Factor (a) (separate, accurate accounting records)

[114] OPA, 2016 Sustainability Assessment: The Title X program (Feb. 2017).

relates to financial separation. In light of those concerns, the Department is finalizing § 59.19's transition provisions so that the physical separation requirements of § 59.15 will have a compliance date (by which covered entities must comply with the physical separation requirements of the section) of one year after publication in the **Federal Register**. The financial separation requirements of § 59.15 will have a compliance date of 120 days after publication in the **Federal Register**. During that transition period, Title X projects will still be required to comply with the financial separation requirements of the 2000 regulations, and accompanying guidance that the Department has published concerning financial separation. Title X projects may transition to compliance with the physical and financial separation requirements of § 59.15 prior to the respective compliance dates if they choose to do so.

Regarding the remaining comments, the Department rejects the comment that it should not finalize the rule because physical separation reinforces the notion that abortion is not a normal part of health care. It is Congress that singled out abortion as an impermissible activity for Title X projects when it specified that it will not fund Title X projects where abortion is a method of family planning.[115] The Department is merely implementing that determination by Congress in a legally permissible manner by determining that there should be physical separation between Title X projects and abortion as a method of family planning.

The Department likewise rejects the suggestion that the rule will impede training for residents in obstetrics and gynecology because the rule will force abortion clinics to close. This final rule does not require clinics that perform abortions to shut down; it only requires that Title X programs maintain physical and financial separation from any provision of abortion. Residents in obstetrics and gynecology will be able to continue their training on family planning methods and services in Title X clinics or at other clinics that provide abortion services. Such training is not impeded by this final rule.

Although the Department takes seriously the concerns raised about potential violence to locations where abortion services are provided, the Department views those concerns as misplaced objections to this rule. Congress chose not to use Title X funds to support programs where abortion is a method of family planning, and the Department has determined that a clear separation between Title X projects and locations offering abortion services is the most appropriate means of implementing that requirement. In order to comply with statutory program integrity provisions to separate Title X funds from facilities where abortion is a method of family planning, the Title X project should not be intermixed with such abortion services. The Department believes that having signs and other forms of materials referencing or promoting abortion present together with Title X materials will confuse the patient regarding what Title X allows. In addition, the Department believes clinic signs must be clear in identifying Title X services versus abortion services. All such requirements avoid confusion regarding what are Title X services and what are not Title X services. Congress has separately provided protections for locations offering abortion services. *See, e.g.,* 18 U.S.C. 248.

Title X authorizes the Secretary to promulgate regulations governing the program. 42 U.S.C. 300a–4. The Department has exercised this authority through regulations to guide Title X grantees in carrying out the program. The Department disagrees with commenters who assert that Title X programs have insufficient guidance on how to apply the physical and financial separation requirements. The Department has included the factors it considers for physical and financial separation of Title X project or facility from prohibited activities in § 59.15. The Department will also take individual circumstances into consideration. For example, a Title X service site might be a hospital that also performs some abortions. However, there is likely less chance of confusion between the hospital's family planning services and abortion services. There are many and diverse centers within the hospital, often in different locations within the hospital building or complex, with different entrances, signage, waiting rooms, and protocols. In addition, it is highly unlikely that a Title X clinic and abortion facilities would be collocated within a hospital building or complex. As long as the Title X clinic and the hospital facilities where abortions are performed are not collocated or located adjacent to each other within a hospital building or complex, it is highly likely that the hospital is not violating the requirement that there be physical separation between the Title X funded activities and activities related to abortion as a method of family planning. By contrast, in a free-standing clinic, physical separation might require more circumstances to be taken into account in order to satisfy a clear separation between Title X services and abortion services. A free-standing clinic would likely present greater opportunities for confusion between Title X and abortion services, including, for example, the same entrances, waiting rooms, signage, examination rooms, and the close proximity between Title X and impermissible services.

The Department does not believe that the physical and financial separation requirement will lead to the mishandling of patient data, as some commenters suggest. Separate EHR systems may lead to two separate electronic medical records, but that is no more burdensome than if the clinic only offers specific services and the patient needs to go to a separate clinic for other needed health care services. It is not uncommon for people to have different health care providers for different health care needs. If Title X services and abortion services are separate, it is no more difficult for Title X providers to maintain two electronic records, one for Title X services and another for abortion services, than to keep abortion services and other services separate within the same EHR system. Moreover, because of growing interoperability of EHRs and other health IT, it is a simpler matter for one provider to share a patient's EHR with another provider—thus, any risk associated with mishandling or missing patient data should be minimized.

Finally, the Department has considered comments on whether the rule should also require, not just physical and financial separation between Title X projects and programs where abortion is a method of family planning, but also organizational separation, and/or provisions such as a requirement that a Title X clinic must operate under a distinct name from a facility that provides abortion as a method of family planning. After considering all the comments and balancing the Department's need to transition to and implement the proposals it is finalizing in this rule, the Department has concluded that, at this time, it will not finalize this rule to add a requirement of organizational separation or name separation, beyond the requirement for physical and financial separation.

[115] It is also Congress that prohibits the use of Title X funds to pay for any abortions and the use of other federal funds to pay for abortions, except in cases of rape, incest, or where the life of the mother is endangered unless an abortion is performed.

K. Prohibition on Activities That Encourage, Promote or Advocate for Abortion (42 CFR 59.16)

Summary of changes: In the first two sentences of proposed § 59.16(a), the proposed rule would require that ''[a] Title X project may not encourage, promote or advocate abortion as a method of family planning. This restriction prohibits actions to assist women to obtain abortions or to increase the availability or accessibility of abortion for family planning purposes.'' The Department finalizes the title and first two sentences of proposed § 59.16(a) as § 59.16(a)(1), with a change to clarify, in response to comments, that the prohibitions apply in the Title X project, not to a grantee's or subrecipient's activities outside of the Title X project and with respect to abortion as a method of family planning, as explained above in response to comments discussed in the section of the preamble addressing § 59.14(a).

The proposed third sentence, and paragraphs (a)(1) through (6), of § 59.16 would specify that the prohibitions include various activities. Paragraph (b) gives examples to illustrate how the proposed prohibitions and specific items listed in § 59.16(a) would apply.

The Department finalizes the third sentence, and paragraphs (a)(1) through (5), of § 59.16 without change, except for formatting changes to improve readability, as § 59.16(a)(2)(i) through (v). The Department finalizes paragraph (a)(6) of the proposed rule in § 59.16(a)(2)(vi), as modified in response to comments. The Department finalizes § 59.16(b)(2) and (3) with changes for clarity in response to comments, as discussed below, and otherwise finalizes § 59.16(b) without change.

Comments: In the discussion of § 59.14(a), the Department addressed comments concerning prohibitions on referral for, and encouragement, promotion, advocacy, support, and assistance of abortion. The Department does not repeat those comments and responses here to the extent they overlap with the comments concerning the specific actions listed in paragraphs (a)(1) through (6) of § 59.16, or the examples explained in paragraph (b).

The Department received various and conflicting comments about its legal authority to enact this section. Some commenters argue the Department is exceeding its statutory authority by impermissibly limiting providers' non-Title X activities and by limiting speech and activities by defining such activities as lobbying. Some of these commenters assert the Department does not adequately explain why the prohibitions on advocacy, lobbying and political activities are justified, stating that it is unreasonable to impose the cost of complying with the proposed rule with no justification. Other commenters contend the proposed rule sufficiently protects free speech by prohibiting the encouragement, promotion or advocacy of abortion by Title X projects but not outside of those projects. These commenters further defend the proposed rule on First Amendment grounds by supporting the Department's rescission of the paragraph in § 59.5 that required Title X providers to counsel on, and refer patients for, abortion.

Some commenters state that the proposed language in § 59.16 is vague, making it difficult to discern what is permissible under the proposed rule, causing confusion, and leading to a prohibitory effect on activities paid for with non-Title X funds. Some of those commenters state that the vagueness may lead to decreased participation in the program or the exclusion of qualified providers, reducing access to care for many patients. Some commenters contend that, to comply with the restriction not to pay affiliation dues or disseminate materials with non-Title X funds, grantees would need separate facilities, and this would lead to the isolation of family planning centers that receive Title X funding, limitations on access, and decreases in the quality of care.

Other commenters oppose the section as unnecessary, arguing that Title X grantees already receive sufficient guidance on what is and is not a permissible use of funding, and that the Department has power without this rule to remedy any findings of noncompliance.

Still other commenters support the proposed rule, and assert that the Department should add additional activities to § 59.16, activities that would be considered as promoting abortion. They ask the Department to provide a wider list of prohibited activities in order to avoid confusion. One commenter provided a list of additional activities that should be prohibited.

Multiple commenters express concern about the proposed rule's impact on State law. For example, commenters write that § 59.16 is not consistent with California's Reproductive Privacy Act and Healthy Youth Act. Some commenters contend that, in New York, organizations that can apply for funding through Title X are already prohibited from funding or engaging in any kind of lobbying activities, rendering this section unnecessary.

Response: As noted above, the Department has slightly modified § 59.16(a) to more clearly explain it applies to actions undertaken within the Title X project, not actions and speech undertaken by Title X grantees (and subrecipients) outside the Title X project. This, and the discussion above, of the Supreme Court's rejection of First Amendment challenges to the 1988 regulations, which had substantially the same provisions, adequately addresses commenters concerns that § 59.16 fails to adequately protect free speech. The Department clarifies again that nothing in this rule restricts the use of non-Title X funds.

In *Rust* v. *Sullivan,* the Supreme Court upheld similar regulations ''broadly prohibit[ing] a Title X project from engaging in activities that 'encourage, promote or advocate abortion as a method of family planning.'' *Rust,* 500 U.S. at 180. As in this rule, the general prohibition was followed by a list of prohibited activities that included, with respect to abortion as a method of family planning, ''lobbying for legislation that would increase [its] availability,'' ''developing or disseminating materials advocating'' it, ''providing speakers to promote'' it, ''using legal action to make [it] available in any way,'' and ''paying dues to any group that advocates'' it. *Id.* The Court concluded a prohibition on such activities is within the Secretary's discretion in implementing section 1008. *Id.* at 184–87. The Court further concluded such conditions did not violate either free speech principles under the First Amendment, or women's rights under the Fifth Amendment. *Id.* at 192–200, 200–203.

The Department concludes that § 56.16 of the final rule does not violate the First Amendment's protections for the same reasons that the Supreme Court held that the 1988 regulations withstood First Amendment challenges in *Rust.* Both this rule and the rule upheld in *Rust* entail the same basic prohibition on encouraging, promoting, and advocating abortion as a method of family planning within the scope of the Title X project, while leaving Title X providers free to undertake any activity they desire outside the scope of the Title X project. This rule contains many of the same illustrations of activities that fall within the prohibition. The list of activities included in the 1988 regulations was non-exclusive, using the same language set forth in this final rule that ''[p]rohibited actions include'' various specific activities. The proposed rule adds some additional examples to those set forth in the 1988 regulations, namely the development of materials

that promote a favorable attitude towards abortion, a reference to web-based materials in that context, and the addition of ''educators'' to the prohibition on ''speakers'' that promote abortion as a method of family planning. Those examples are well within the reasoning of *Rust,* and indeed within the broad prohibition of the 1988 regulations. However, the Department is removing the phrase regarding a prohibition on the use of Title X funds for the production of materials that ''promote a favorable attitude towards abortion.'' The Department makes this change in acknowledgement of some of the commenters who contend the section is vague and subjective, so that it would be difficult for grantees to know what would be a permitted activity and what would constitute an impermissible activity. The Department agrees that the phrase is vague, and believes that prohibiting materials that promote abortion as a method of family planning is clear and sufficient. This final rule also includes some examples prohibiting project funds from being used on lobbying, specifically the use of project funds for attendance at events and conferences where the grantee or subrecipient engages in lobbying, and the restriction on payment of dues to a group that does not separately collect and segregate funds used for lobbying purposes. These clauses implement the specific Congressional prohibition that Title X project funds ''shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.'' [116] As proposed, § 59.16(a)(4) would prohibit ''[p]aying dues to any group that, as a more than insignificant part of its activities, advocates abortion as a method of family planning and does not separately collect and segregate funds used for lobbying purposes.'' The Department considers this provision concerning lobbying to be an appropriate measure to implement Congress's prohibition on the use of Title X funds ''in any way'' for lobbying. [117] As noted above, the Department finalizes this text, and makes corresponding changes to the examples in § 59.16(b)(2) and (3).

The Department appreciates commenters' suggestions of additional activities that should be included in § 59.16(a) as actions that cannot be undertaken in Title X projects, but declines to add to the list of actions in § 59.16(a). The regulatory text indicates that the list is non-exhaustive and that prohibited actions ''include'' the actions listed; it does not indicate that those actions listed are the only actions that fall under the prohibition on encouragement, promotion, or advocacy of abortion as a method of family planning.

The Department disagrees with commenters who contend the provisions will have the effect of pushing providers out of the Title X program, and, therefore, that § 59.16 will have a negative impact on access to care. Much of § 59.16 merely implements the applicable appropriations law provisions; thus, Title X projects should not currently be using Title X funds to engage in such activities. To the extent that § 59.16 incorporates new requirements, the Department concludes that the articulation of those requirements in rulemaking after notice and public comment is an appropriate approach to ensure consistency and compliance with the parameters applicable to Title X. But in any event, nothing in the final rule precludes entities that encourage, promote, or advocate abortion from being grantees or subrecipients, if such activities are undertaken outside the scope of the project and consistent with the physical and financial separation requirements of these rules. Because section 1008 precludes projects where abortion is a method of family planning, if entities are encouraging, promoting, or advocating such abortions within a project, they are diverging from the goals of Title X. By ensuring that Title X project funds are not diverted to activities that encourage, promote or advocate abortion as a method of family planning, or that assist women to obtain abortions for family planning purposes or to increase the availability or accessibility of abortion, the Department anticipates that more project funds will be available to provide the family planning services that Congress intends in its focused approach to Title X's scope.

The Department does not agree that this rule inadequately considers the requirements of State laws. The rule represents implementation of a clear choice by Congress not to fund certain activities in Title X projects. Applicants for Title X funding will need to maintain an awareness regarding State and local laws to which they are subject, as well as the requirements to which they are subject under this final rule.

The Department finalizes the example in § 59.16(b)(2) with a clarifying change. The proposed rule provided a proposed example that established a Title X project violates paragraph 59.16(a) if it makes an appointment with an abortion clinic for a pregnant client. The Department clarifies this example to be more consistent with section 1008 of the PHS Act, which prohibits funding a Title X project where abortion ''is a method of family planning.'' Consistent with that language, as noted above and in the second sentence of § 59.16(a), the provisions of this rule implementing section 1008 apply to ''abortion for family planning purposes.'' Therefore the Department finalizes the example listed in § 59.16(b)(2) to specify that the scenario in question is one where ''[a] Title X project makes an appointment for a pregnant client for an abortion for family planning purposes . . .'' The Department also makes a change to the example in § 59.16(b)(3), so that it illustrates more directly the activity prohibited in § 59.16(a)(2)(iv), by incorporating into the example information about whether the lobbying funds were separately collected and segregated.

L. Compliance With Reporting Requirements (42 CFR 59.17)

Summary of changes: The proposed rule would add § 59.17, which imposes requirements concerning compliance with State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence (IPV) or human trafficking. The Department finalizes this section with changes in response to public comments to clarify notification, screening of minors, and recordkeeping relating to minors; and to expand related topics to be covered in annual staff training.

Comments: Some commenters express support for increased compliance requirements of § 59.17(a) and contend that providing evidence of compliance with all State and local laws would strengthen protection for minors and vulnerable adult populations. Some argue that some Title X entities enable sexual exploitation by failing to institute compliance procedures with State and local laws that would help victims, and they request an investigation into Title X entities to determine the extent of failed abuse reporting. Several commenters favor expanding reporting requirements to include reporting of general criminal conduct unrelated to acts of sexual abuse.

[116] *See* Omnibus Consolidated Rescissions and Appropriations Act, 1996; HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat at 3071.

[117] Title X funds ''shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.'' HHS Appropriations Act 2019, Public Law 115–245, Div. B, 132 Stat. at 3071.

Many commenters state that the proposed rule wrongly gives the Department compliance oversight over State and local reporting laws. Several commenters contend that mandated reporting of intimate partner violence (IPV) would prevent patients from speaking candidly with health care providers for fear that their abuse will be reported before they have had the opportunity to protect themselves (and their children, if applicable) financially, legally, and physically from their abusers. Commenters mention that medical records documenting IPV and other abuse issues can be used in legal contexts, putting patients at risk for further violence.

Many commenters note the complexity and variety of State and local reporting laws. Several commenters emphasize that there must be a balance between the protection for victims of abuse, complying with State laws, and trust in the patient-provider relationship. Several commenters note that State laws already include specific requirements that provide clear direction to health professionals regarding their obligations to report and their responsibility to exercise discretion. One commenter argues that federal and state laws should support physicians in their clinical judgment. Other commenters contend that allegations of providers avoiding reporting responsibilities are without evidence and should not be a basis for policy-making.

In reply to the Department's request for comment on whether a referral agency (to which a Title X project refers) should be subject to the same reporting requirements as a grantee or subrecipients subject to § 59.17, some commenters state there is no need for a referral agency to be subject to the same reporting requirements as a grantee or subrecipient. Several commenters state that community partners and referral agencies are not Title X funded entities, are often overburdened and additional requirements may cause referral agencies to terminate collaborative relationships rather than comply with the new reporting requirements, thereby reducing patients' access to health care.

Some commenters contend that Department enforcement of the provisions of § 59.17(b), including the threat of revocation of funding based on whether providers comply with State and local reporting requirements, would increase pressure on Title X projects to over-report abuse and to engage in ''excessive policing,'' thus traumatizing patients through interrogative questioning. They also contend the rule would erode patient-provider trust, put patients at risk for serious harm, re-victimize patients that have experienced trauma, stigmatize patients that are sexually active, and negate personal agency for adolescents.

Many commenters contend that mandatory screening raises issues regarding confidentiality for adolescents and minors, noting that the Title X protections for patient confidentiality are some of the strongest under current law.

A few commenters mention that the proposed rule would result in increased cost for screening and reporting, specifically noting the transition to electronic health record templates. A few commenters note that this would lead to decreased care and family planning options for patients, resulting in increased costs for unintended pregnancies.

Many commenters fear, in particular, that screening minors with a sexually transmitted disease (STD), pregnancy, or suspicion of abuse would be harmful to patients and detrimental to the provider-patient relationship, compromising trust and honesty in consultations. Many argue that mandated screening would shift the provider role to that of an interrogator, making young people less likely to reveal abuse, and making them less likely to return to the Title X facility. One commenter argues that the age of a teenager's sexual partner does not have bearing on family planning services. Others contend that mandatory screening would deter patients from seeking family planning services and treatment for STDs, resulting in increased pregnancy and STDs.

Other commenters assert that screening should only be required for patients that show signs of abuse. Commenters argue that the screening is unnecessary, as Title X grantees already are mandated to adhere to Federal and State notification requirements. Some commenters note that the proposed rule may conflict with Medicaid coverage, which permits confidential family planning services for individuals of childbearing age, suggesting that it creates confusion as to who must be screened.

Several commenters support a commitment to confidentiality, but also support the new rules as an important safeguard for minors who may be the victims of sexual abuse. One commenter recommends that projects be required, rather than permitted, to diagnose, test for, and treat STDs.

Finally, some commenters describe instances in which they claim the language of the proposed rule is confusing. For example, they contend that required screening for patients ''under the age of consent in the State'' is inconsistent with the requirement for Title X projects to implement a plan committing to preliminary screening of teenagers with a sexually transmitted disease (STD), pregnancy, or any other suspicion of abuse. Such commenters suggest the language be re-written to clarify the intent.

Response: The Department agrees with commenters who voice support for § 59.17 to ensure those vulnerable to abuse are protected in Title X projects. The Department takes seriously the duty of Title X grantees and subrecipients to comply with State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. Congress has specifically emphasized the importance it attaches to compliance with such laws by Title X funding recipients. As stated in the most recent appropriations act, ''[n]ot withstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.'' [118] The Department interprets that direction to include State or local laws respecting intimate partner violence (IPV) and human trafficking. In addition, the Secretary has authority under section 1006 of Title X to issue regulations governing grants and contracts in the Title X program. Thus, to ensure compliance with this Congressional mandate, the Department believes it is appropriate to include specific regulatory requirements with respect to the care and treatment of survivors of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking within the context of the provision of family planning services, and the reporting or notification of such criminal acts under State and local notification laws in § 59.17. The Department disagrees with commenters who assert that the Department does not have the authority to oversee compliance with reporting the listed crimes by Title X providers in Title X projects.

The Department understands the sensitivity that comes with IPV, but concludes that, if a State or local jurisdiction has enacted laws to require reporting of IPV by entities that are Title X grantees or subrecipients, it is appropriate for the Department to ensure that such entities comply with

[118] HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 208, 132 Stat. at 3090.

those laws as a condition of receiving Title X funds. Title X providers may be the first health care touchpoint for the survivors of IPV. As such, they should be prepared and trained not only to treat such individuals with dignity and care in addressing such individuals' family planning needs, but also to refer them for other needed health care and to report such IPV to the appropriate authorities. State and local reporting laws that include IPV do so, among other reasons, because of its connection to poverty, because most IPV victimizes women, and because intimate partner homicides make up 40% to 50% of all murders of women in the United States.[119] Moreover, IPV may include rape, sexual abuse, and/or other crimes expressly addressed in the Title X appropriations provision. The Department considers these reasons sufficient to include IPV in the reporting requirements of this rule.

The Department acknowledges that complying with State and local laws may be complicated, and for that reason Title X grantees and subrecipients must have in place a plan that ensures that the grantee and any subrecipients are aware of what specific reporting requirements apply to them in their State (or jurisdiction), and provide adequate training for all personnel with respect to these requirements and how such reports are to be made. The complexity of those laws is not an excuse for non-compliance, and the Department will not tolerate Title X grantees and subrecipients failing to comply with the reporting requirements that State and local governments have seen fit to enact as binding legal requirements. The proposed rule at § 59.17 defers to State and local jurisdictions on what reporting requirements apply, and in this way fully respects Federalism and the proper jurisdiction over such crimes that is exercised by State and local governments. The proposed rule does not add any substantive reporting requirement that State and local jurisdictions do not already impose; the rule simply ensures that the Title X grantees and subrecipients are in compliance with federal law by ensuring that such grantees and subrecipients are in compliance with State and local reporting requirements.

As several commenters note, State and local laws can be vital resources in crafting protocols since they often provide direction to health professionals regarding how to balance their obligations for reporting with the exercise of discretion to best protect the safety of the victim. As part of prevention, protection, and risk assessment efforts, grantees and subrecipients should include compliance protocols to identify individuals who are victims of sexual abuse or who are targets for underage sexual victimization, as well as to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities (as required by appropriations law applicable to Title X).

The Department believes that increased compliance requirements strengthen protection for minors and other vulnerable populations. The proposed rule, and this final rule, at § 59.17 explicitly address the requirement for Title X projects to comply with all State and local laws regarding the notification or reporting of crimes involving sexual exploitation, child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking (collectively, ''State notification laws''). The Department's Office of Inspector General (OIG) issued a 2005 report revealing that even though OPA informs and periodically reminds Title X grantees and subrecipients of their responsibilities regarding State child-abuse and sexual-abuse reporting requirements, it could not determine the extent to which grantees actually comply with these requirements.[120] The Department believes that minors and other vulnerable communities are better served if Title X providers are accountable for complying with these State and local laws.

The Department is also sensitive to concerns raised by commenters that victims of abuse are sometimes repeatedly victimized after abuse is reported. Therefore, the Department expects grantees and subrecipients to include additional training in their protocols to assist counselors with their interactions with a victim of abuse and to ensure that they are equipped to make referrals that increase the safety of the patient. The regulatory text is updated to reflect this additional component of training for Title X staff in paragraph (b)(1)(ii) of § 59.17. The final rule adds that the policies will include training regarding State notification laws and ''appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient. . . .''

The Department has considered the request of some commenters to broaden the reporting requirements even further. The Department concludes, however, that the proposed language is consistent with language that has been included in appropriations acts for the Department since fiscal year 1999.[121] Additionally, the Department has considered some commenters' requests to further investigate the specific entities which the commenters allege have misappropriated Title X funds. The Department believes that the clarification of reporting requirements found in the rule will remedy any confusion about the use of Title X funds. The Department will investigate any credible report of fiscal abuse or misuse of funds and take appropriate action, if found.

Having considered the comments about whether to broaden the reporting requirements to include entities that are not grantees or subrecipients, such as referral agencies, the Department agrees with commenters who state that referral partners should not be subject to the same reporting requirements. Referral agencies do not receive Title X funds, therefore, the Department declines to make changes in § 59.17 that would expand the provision to impose reporting requirements on entities that are neither recipients nor subrecipients of Title X funds.

The Department disagrees with commenters who say the training and reporting requirements in the proposed rule will lead to over-reporting or erode patient trust and confidentiality. Title X grantees and subrecipients are already subject to State and local reporting laws, and Congress has made it clear that the receipt of Title X funds does not permit Title X grantees and subrecipients to avoid such obligations. In addition, § 59.11 of the 2000 regulations permits the use of confidential information obtained by project staff to comply with State and local reporting requirements. The Department will not second guess the determinations of States or local governments that these reporting requirements do not erode patient trust and confidentiality, but protect vulnerable persons. The Department is not aware of compelling evidence to the contrary from commenters. The Department also hopes that victims of

[119] Office of Justice Programs, *Causes and Consequences of Intimate Partner Violence,* National Institute of Justice (Oct. 24, 2007), *https://www.nij.gov/topics/crime/intimate-partner-violence/Pages/causes.aspx.*

[120] HHS OIG, OEI–02–03–00530, *Letter on Federal Efforts to Address Applicable Child Abuse and Sexual Abuse Reporting Requirements for Title X Grantees* (Apr. 25, 2005), *https://www.hhs.gov/opa/sites/default/files/child-abuse-reporting-requirements.pdf.*

[121] *See, e.g.,* Department of Health and Human Services Appropriations Act, 1999, Public Law 105–277, Title II, sec. 219, 112 Stat. 2681, 2681–363 (1998).

abuse will feel increased trust with Title X providers as a result of the training required in the final rule, not only with respect to compliance with State and local reporting laws, but also how to offer strategies to improve the victim's current situation, including the patient's safety.

The Department disagrees with commenters who assert the regulations will abrogate confidentiality for minors, stigmatize them, cause them to lose their personal agency, or violate their informational privacy rights. All recordkeeping, except that which must be submitted as a result of mandatory reporting, is subject to the same confidentiality requirements as other medical services rendered by the clinic. If a minor is a suspected victim of abuse, the Title X provider has the obligation to report suspected abuse,[122] make appropriate referrals if needed, and empower the minor with skills to build self-efficacy and the self-confidence to resist any future sexual coercion.[123]

The Department disagrees with some commenters who contend the age of a minor's sexual partner has no relevance for Title X grantees. State and local reporting laws concerning sexual abuse or child abuse often have elements concerning the age of the minor and the minor's sexual partner. Title X exempts neither Title X providers nor Title X health care providers from their responsibility to comply with State and local reporting laws. Child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking are crimes that affect individuals, families, and communities. Title X projects should be the exemplar of an appropriate model for protecting those who are vulnerable to sexual abuse, rape, and assault; in developing protocols to identify clients who may be at risk for sexual abuse; in counseling teens on, and in producing programs and materials that assist teens in, resisting sexual exploitation, abuse, and coercion;[124] and in assuring appropriate support and management of teens (and women and men) who have been exploited, abused or coerced into unequal sexual partnerships. The Department believes asking the right questions can identify victims of abuse for mandatory reporting purposes, protect them from continued victimization, and help them access services to increase their health and safety in the future. With regard to comments concerning the requirement in § 59.17(b)(2)(ii) to maintain records including those which ''[i]ndicate the age of the minor client's sexual partners where required by law,'' the Department clarifies what is meant by that paragraph by finalizing it to read, ''[i]ndicate the age of the minor client's sexual partners if such age is an element of a State notification law under which a report is required. . . .'' The Department does not believe that conforming to the reporting requirement will result in a regulatory burden or increased costs for reporting to State and local authorities, since grantees and subrecipients should already be complying with this mandate.

The Department disagrees that required sexual abuse/victimization screenings are harmful to patients. Similar to typical components of a medical history, Title X projects are already required to conduct a preliminary screening of any teen who presents with an STD, pregnancy, or suspicion of abuse in order to rule out victimization of a minor. Such screening is required with respect to any individual who is under the age of consent in the jurisdiction in which the individual receives Title X services. If positively diagnosed, projects are permitted to treat STDs as an appropriate preconception service. The requirement in the final rule is more explicit in the age parameters in order to offer consistency from State to State and to ensure that this requirement consistently applied throughout all Title X services areas. This requirement is responsive to both State notification laws as well as the appropriations rider related to sexual coercion of minors. The Department does not believe, as some commenters suggest, that Title X providers should be required to diagnose, test for, and treat STDs, although testing and treatment would be an appropriate referral service, if not offered onsite. Sites must offer a variety of family planning services, but are not required to provide all such services. As an important component of the screening process, staff would sensitively converse with patients and build trust, while obtaining the information needed to comply with the screening and reporting requirements.

The Department disagrees with commenters who assert the rule conflicts with Medicaid coverage confidentiality requirements. The rule requires screening for minors who are pregnant or test positive for STDs. The preliminary screening is used to determine whether the minor is a likely victim of sexual coercion, a concern of Congress, as evidenced by its specific mandate that Title X projects provide ''counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.''[125] While Medicaid and Title X both allow family planning services to be provided confidentially to individuals of childbearing age, providers serving patients who use Medicaid must still do their due diligence to ensure they are complying with all State and local reporting requirements, and if Title X grantees, with the appropriations riders applicable to the program. In light of State and local laws against incest and laws regulating age-specific requirements for permitting sexual relations with minors, the Department believes that mandatory screening of minors ensures that Title X providers are adequately assessing their legal requirements under State and local law, the protection to minors sought in the appropriation rider, and the patient's overall health. The Department is specifically directed to focus Title X grantees on these issues: Appropriations law provisions requires Title X applicants to certify that it ''provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities''[126] and requires Title X providers to comply with State notification or reporting laws on child abuse, child molestation, sexual abuse, rape, or incest. The confluence of these two separate, but related, mandatory provisions are addressed in this Section.

The Department disagrees with commenters who assert only those with visible signs of abuse should be screened or that screening is unnecessary. Pregnancy, or the presence of an STD, can be evidence of abuse or a predictive sign of abuse, especially among younger minors. Often victims

[122] As Representative Ernest Istook said during the debate regarding the provision: ''It says, if there is a situation, such as I described, involving an underage child, Title X providers must report that and comply with State law the same as anyone else who deals with services to our young people.'' 143 Cong. Rec. H7053 (daily ed. Sept. 9, 1997).

[123] HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[124] As noted above, the annual appropriations laws also impose on Title X grantees the obligation to provide ''counseling to minors on how to resist attempt to coerce minors into engaging in sexual activities.'' *See* HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[125] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495; HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

[126] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495; HHS Appropriations Act 2019, Public Law 115–245, Div. B, sec. 207, 132 Stat. at 3090.

do not self-identify and may have no obvious indicators at all, elevating the necessity of screening. The Department believes that a confidential and empathetic screening process will enable a program to better serve those individuals who have been victimized and to identify those instances where state or local law requires notification of certain crimes.

The Department agrees with some commenters who observe that the language of the proposed rule is inconsistent in referring to a ''minor'' several times, an individual below the ''age of consent'' in another place, and to a ''teen'' in the first part of the first sentence of § 59.17(b)(1)(iv). The Department intended the rule to refer to ''minors'' in all such instances, and finalizes § 59.17(b)(1)(iv) to change the word ''teen'' to ''minor;'' and to remove the sentence referencing ''age of consent'' in relation to State laws, since preliminary screening for minors would be separate from, but inclusive of, ages included in individual State notification laws.

Although § 59.17(a) defines the term ''State notification laws'' for the purposes of the section to refer collectively to ''all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking'', the prefatory text of § 59.17(b)(1) mistakenly uses the phrase ''State laws'' instead of ''State notification laws.'' The Department therefore finalizes § 59.17(b)(1) prefatory text to change the phrase ''State laws'' to ''State notification laws,'' consistent with the intent of the proposed rule.

M. Appropriate Use of Funds (42 CFR 59.18)

The 2000 regulations required that any Title X funds must be expended solely for the purposes for which the funds were granted. The proposed rule would add § 59.18, which clarifies this language by detailing the prohibited uses of Title X funds, including their use for abortion-related infrastructure building, lobbying activities, and any other possible misuse of funds. The Department finalizes the section without change, except to make technical edits that improve understanding and readability.

Comments: Many commenters that object to § 59.18's proposed prohibition on uses for Title X funds, including limits on infrastructure building, and raise objections that overlap with their objections to the proposed requirements of § 59.15 for physical and financial separation of Title X projects and prohibited activities. The Department's response to those comments above encompasses those objections.

Some commenters support the proposed language of § 59.18 prohibiting the use of Title X funds for building infrastructure that supports a Title X grantee's abortion-related activities. Commenters state that the proposed changes will help ensure that Title X funds are correctly appropriated. Others believe the rule should go further and require grantees or subrecipients to demonstrate that they do not fund abortion services with Title X funds.

Some commenters contend it is unnecessary for the Department to prohibit the use of Title X funds to support abortion services, infrastructure building for that purpose, or lobbying. They contend current accounting, reporting, and auditing requirements already ensure that each Title X project fully accounts for and justifies charges against the Title X grant.

Response: The Department agrees with commenters who support the proposed language at § 59.18.

The Department disagrees with commenters who suggest that there have been no concerns raised regarding improper use of Title X funds. The Department believes that, even if the extent of such misuse of funds is not fully known, the Department is still legally obliged to ensure funds are not misused, so it is appropriate for the final rule to identify what constitutes such misuse of Title X funds. Increased transparency will ensure greater accountability for the use of Federal funds and will mitigate confusion about what services the federal government supports and funds.

As explained in the proposed rule, the flexibility in the use of Title X funds under the 2000 regulations raises concerns about the fungibility of assets that could be used to build infrastructure for abortion services. By law, Title X providers must secure other sources of revenue to leverage Title X grants. 42 CFR 59.7(c) (''No grant may be made for an amount equal to 100 percent for the project's estimated costs.''). Medicaid providers are reimbursed by States for allowable expenditures. By their very nature, grants afford considerably greater latitude and versatility to grantees on how funds are used. If an organization receives both Medicaid and Title X funding, for example, Medicaid reimbursement payments might be used to cover many family planning services, freeing up Title X funds to be used for infrastructure-building and support. In its *Moving Forward: Family Planning in the Era of Health Reform* report, the Guttmacher Institute reported that providers do in fact use Title X funds in this way:

> Up-front funding helps supply a cash-flow cushion for providers who are often operating on tight and uncertain budgets. More specifically, Title X grantees use the program's flexible grant funding in a variety of ways to address staff-related issues, including hiring individuals capable of meeting communities' need for linguistic or culturally appropriate care, training staff on the latest medical techniques or to provide tailored counseling for clients with special needs, maintaining sufficient staff to operate outside regular business hours and paying sufficient wages to staff at all levels to reduce high turnover rates that often plague health centers. Providers may also use Title X funds for operational investments, such as utilizing advanced technologies and facilitating more accessible and efficient client care . . . . Finally, Title X undergirds the infrastructure and general operations of the health centers themselves in ways that Medicaid and private insurance simply cannot. Title X funds go to centers up front as grants, rather than after the fact as reimbursement for services centers have provided to individual enrollees. Providers have long relied on that flexibility to hire, train and maintain their staff to meet the diverse needs of their clients and community. They have also depended on these grants to keep their lights on and their doors open, to adapt to unexpected budget shortfalls and to make improvements to their facilities. Such versatility is even more vital in the era of health reform. The up-front investments in staffing, training and infrastructure needed to work effectively with health plans—and to thereby draw in new revenue to serve more clients—are substantial, and flexible funds like those provided through Title X are ideal for such investments. Those expenses include upgrading health information technology systems and training staff on their use, training clinicians and front-line staff to properly code and bill for services provided, obtaining the appropriate credentials to ensure third-party reimbursement, and devoting time and resources to researching available health plans and negotiating contracts with them. They may also include expenses related to outsourcing some administrative functions to private contractors or as part of collaborations with other health care providers.[127]

In a 2007 report, Guttmacher expanded upon the infrastructure support afforded by Title X funding:

> Title X can subsidize the intensive outreach necessary to encourage some individuals to seek services. Furthermore, by paying for everything from staff salaries to utility bills to medical supplies, Title X funds provide the essential infrastructure support that enables clinics to go on and claim

[127] Sonfield, A., Hasstedt, K., Gold, R.B., Moving forward. Family planning in the era of health reform, Guttmacher Institute 30 (March 2014), *https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.*

Medicaid reimbursement for the clients they serve.[128]

Infrastructure building may include securing physical space, developing or acquiring health information technology systems (including electronic health records), bulk purchasing of contraceptives or other clinic supplies, clinical training for staff, and community outreach and recruiting. An anecdotal story [129] from the 2007 report reinforces the point:

> Ibarra of California's Venice clinic says her agency sends street outreach teams into the community with backpacks of condoms and basic educational materials, while other teams make regular visits to homeless shelters. Often, it will take multiple visits to a shelter or street-corner conversations until someone feels safe enough to come to a clinic. According to Ibarra, Title X will fund and train the outreach workers, purchase the condoms and often even develop the educational materials they distribute. Only when a client actually comes to the clinic is reimbursement available (through Medicaid or any other source), and then only if the client qualifies. According to Annette Amey, director of program evaluation for CFHC, ''it's all about getting people to the inside of the clinic door, and for that Title X dollars are indispensable.''

The Department is concerned about this infrastructure building on both statutory and policy grounds. As a statutory matter, the use of Title X funds to build infrastructure that can be used for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient, clearly violates section 1008. As a policy matter, Title X is the only discrete, domestic, Federal grant program focused solely on the provision of cost-effective family planning methods and services. As the number of Americans at or below the poverty level has increased, the need to prioritize the use of Title X funds for the provision of family planning services has as well.

The Department concludes it is appropriate to implement the statutory requirements applicable to Title X by imposing the § 59.18 restrictions addressing the use of Title X funds for infrastructure purposes related to abortion, particularly in combination with the § 59.15 requirement of physical and financial separation of Title X projects from prohibited activities (*e.g.,* abortion as a method of family planning). Because Title X projects would not share any infrastructure with abortion-related activities, direction of Title X funds toward such infrastructure would no longer threaten to divert funds to impermissible activities. That separation would thus ensure that Title X funds are used for the purposes expressly mandated by Congress, that is, to offer family planning methods and services—and that any infrastructure built with Title X funds would not be used for impermissible purposes.

N. Transition Provisions (42 CFR 59.19)

Summary of changes: The proposed rule would add § 59.19, which specifies the effective dates and compliance dates of the provisions of the proposed rule. The Department finalizes this provision with changes to the compliance dates in response to public comments, and makes some minor formatting and technical edits to improve readability.

Comments: Many commenters contend transition periods by which covered entities must comply with the rule are not long enough. Some recommend lengthening the physical separation transition period from one to two years, while many recommend extending the period to three years. Some contend they do not know how long would be needed for compliance, but at least an additional year is needed. Various commenters worry that many Title X recipients would be unable to receive care while clinics are in the process of separating after the proposed one year time period expires.

One commenter asks that the changes be scheduled to take effect at the end of the project period during which the rule is finalized in order to limit confusion for current grantees. One commenter suggests that Title X create different transition requirements for different Title X providers based on resource-level, location revenue, and client population.

Additionally, one commenter notes the cost of establishing new Electronic Health Record (EHR) systems would include the costs for new hardware and infrastructure for these systems. In New York State, providers may not purchase equipment in the final year of a grant cycle. Since 2019 is the final year of the grant for New York State Family Planning projects, the commenter contends that these providers would be unable to comply with the new requirements until a new grant is issued.

One commenter requests that the financial transition period be lengthened from 60 days to six months, stating that, according to businesses that provide modification and implementation of EHR systems, six months, at minimum, is needed. The majority of commenters recommended changing the transition period to one year for financial separation.

Response: The effective date for all sections of the final rule is 60 days after publication of this rule in the **Federal Register**, as set forth in the Dates section of this notice. Except with respect to the provisions for which the Department establishes a separate compliance date, covered entities will be expected to comply with the requirements of this final rule by that date.

The Department extends some of the compliance dates of certain sections or paragraphs in the rule, by which covered entities must comply with those sections after their effective date, in response to public comments as follows.

The Department maintains the compliance date of one year for the physical separation requirements of § 59.15. The Department disagrees with commenters who contend one year is an insufficient time period for covered entities to comply with the physical separation requirement of the rule. The Department believes one year is an ample and generous amount of time for an entity to rearrange locations, find new locations, comply with related State requirements, or even make changes to a facility to physically separate Title X services from abortion services. These rules might be satisfied by placing Title X projects (or the abortion services) in a different location without changing any physical or facility space. It is not uncommon for health care providers to change locations, change their physical space, or even add new service delivery locations. As a result, the Department disagrees with commenters who assert that patients will lose service because of the physical separation requirement would apply beginning one year after the publication of the final rule.

The Department agrees with commenters who contend some other components of § 59.15, such as those pertaining to electronic health records, should also be subject to the one-year separation requirement. The Department considers the electronic health records to pertain to physical separation and, thus, subject to the one-year compliance deadline. However, the Department will require that Title X projects and providers comply with the requirement of financial separation by July 2, 2019. The Department therefore finalizes paragraph (a) of the transition rule specifying the compliance date for the physical separation requirements contained in § 59.15, by which covered entities must comply with such requirement, as March 4, 2020. Title X projects may comply with the physical

[128] Gold, R.B., *Stronger Together: Medicaid, Title X Bring Different Strengths to Family Planning Effort,* Guttmacher Institute 15 (May 17, 2007), *https://www.guttmacher.org/gpr/2007/05/stronger-together-medicaid-title-x-bring-different-strengths-family-planning-effort.*

[129] *Id.* at 17.

separation requirements of § 59.15 earlier than the one year compliance date if they choose, and may comply with the financial separation requirements of § 59.15 earlier than the 120 day compliance date if they choose. Prior to the compliance date for the financial separation requirements of this final rule, the Department expects that grantees will comply with the ''Separation'' section of the guidance at 65 FR 41281, 41282, or with the financial separation requirements of § 59.15.

Various parts of the final rule impact applications for grants, namely § 59.7, the removal of § 59.5(a)(10)(i), and § 59.5(a)(13) as it applies to grant applications. The Department intends that these requirements will apply prospectively to applications for competitive or continuation awards, but not to applications that have been submitted before publication of the final rule or that are due in a time period soon after publication of the final rule. The Department intends that these provisions will apply to applications for which the Department has informed the applicant these provisions will apply. Therefore, the Department finalizes paragraph (b) of the transition section to establish that the compliance date for covered entities regarding § 59.7, the deletion of § 59.5(a)(10)(i), and § 59.5(a)(13) as it applies to grant applicationswill be the date on which competitive or continuation award applications are due, where that date occurs after July 2, 2019.''

The Departments have carefully reviewed comments seeking more time for implementation of requirements for reporting, submitting assurances, and providing certain services. These sections include §§ 59.5(a)(12), 59.5(a)(13) as it applies to all required reports, 59.5(a)(14), (b)(1) and (8), 59.13, 59.14, 59.17, and 59.18. In response to the request by commenters that more than 60 days is needed for compliance with such requirements, the Department has concluded that it will finalize the transition section to allow 120 days for compliance with this section. The Department believes this provides sufficient time for grantees and subrecipients to comply with these requirements. Therefore, the Department finalizes paragraph (c) of the transition section to establish the compliance date for covered entities regarding § 59.5(a)(12), § 59.5(a)(13) as it applies to all required reports, § 59.5(a)(14), § 59.5(b)(1), § 59.5(b)(8), § 59.13, § 59.14, § 59.17, and § 59.18is July 2, 2019.''

The Department concludes that the remaining requirements of the final rules, that is, all requirements not specified above, can be satisfied within 60 days of publication of the final rules in the **Federal Register**, that is, by the effective date. For example, Title X projects can comply with the prohibition on referrals for abortion as a method of family planning within 60 days. Therefore, the Department does not establish a separate compliance date for such provisions of this final rule.

III. Economic/Regulatory Impact and Paperwork Burden

A. Introduction and Summary

The Department examined the impacts of the final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011); the Regulatory Flexibility Act, 5 U.S.C. 601 (RFA); Unfunded Mandates Reform Act, 1995, Public Law 104–4, Title II, sec. 202(a), 109 Stat. 48, 64 (1995); Executive Order 13132 on Federalism (August 4, 1999); the Congressional Review Act, 5 U.S.C. 804(2); section 654, 5 U.S.C. 601 (note), on the Assessment of Federal Regulation and Policies on Families; E.O. 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017); and the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

In addition, the Department carefully reviewed the public comments, and as a result, has updated the estimated costs for implementing the final rule in some cases. Those changes are described below and reflected in the narrative and calculations represented later in this section.

1. Executive Orders 12866 and 13563 and the Congressional Review Act

Comments: Commenters contend that the Administration failed to solicit public input on the proposed rule, citing E.O. 12866, noting that the proposed rule was not included in the Spring 2018 Unified Regulatory Agenda and that public input was not permitted prior to final review.

Commenters contend that the proposed rule qualifies as a ''significant regulatory action'' under E.O. 12866 and E.O. 13563, and maintain that the Economic Impact Analysis performed by the Department failed to address the potential cost to patients and providers. Commenters contend that the Department focused on the benefits and protections of the proposed rule, but failed to adequately address potential problems. For example, commenters contend that the Department did not accurately estimate costs associated with the physical separation requirement, the new definition of ''low income family,'' and unintended births that will result from the regulation.

Response: Although some commenters claimed that this rule would increase unintended pregnancies, the Department disagrees, for the reasons set forth above, and believes this rule will lead to a better or wider distribution of family planning services. In any event, the Department is not aware, either from its own sources or from commenters, of actual data that could demonstrate a causal connection between the type of changes to Title X regulations contemplated in this rulemaking and an increase in unintended pregnancies, births, or costs associated with either, much less data that could reliably calculate the magnitude of that hypothetical impact. Therefore, the Department concludes that those are not likely or calculable impacts for the purpose of the Executive Order.

The Department's impact analysis provides its best thinking on the effects of the proposed rule. It acknowledges that it is difficult to forecast all of its effects, and acknowledges uncertainty regarding the estimates. However, the Department believes that this proposed rule will result in better outcomes for people interested in utilizing Title X family planning services and does not believe that public comments provided substantive evidence of negative effects of the proposed rule.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Under Executive Order 12866, the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs determines whether a regulatory action is significant and, therefore, subject to the requirements of the Executive Order and review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule that (1) has an annual effect on the economy of $100 million or more, or adversely affects in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as economically significant); (2) creates serious inconsistency or otherwise interferes with an action taken or

planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. OMB has determined that this final rule is a significant, but not economically significant, regulatory action under section 3(f) of Executive Order 12866.

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies that issue regulations to analyze options for regulatory relief of small entities, businesses, 501(c)(3) entities, as well as government entities if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of ''small entity.'') The Department considers a rule to have a significant economic impact on a substantial number of small entities if at least 5% of small entities experience an impact of more than 3% of revenue. The Department does not believe that the rule will have a significant economic impact on a substantial number of small entities. Supporting analysis is provided below.

3. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' Public Law 104–4, Title II, sec. 202(a), 109 Stat. 48, 64 (1995). The current threshold after adjustment for inflation is $150 million. The Department does not expect this rule to result in expenditures that would exceed this amount.

4. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has federalism implications.

Comments: Commenters contend that the Department is preempting State law (without approval from Congress) by eliminating abortion referral and counseling requirements for Title X projects. Commenters assert that the Department failed to obtain State and local government input on the proposed rule, and failed to provide a comprehensive analysis for the Federalism implications of the proposed rule, which would have included a summary of the concerns expressed by State and local government officials. Commenters note that the Department included a federalism impact statement in a 2016 effort to revise Title X eligibility funding and argued that one should be required for this rule as well. Commenters recommend that an analysis be conducted that will assess how to address potential conflicts between the rule and State law. Commenters assert that State and local entities qualify as Title X grantees or subrecipients and would incur increased costs associated with providing access to services no longer provided by Title X, as well as costs associated with reduced access to those services for the public.

One commenter stated that the Department did not adequately assess the impact of the NPRM on individuals' health and well-being, as is required under Public Law 105–277. According to the commenter, the Department provided no details of an assessment in the NPRM, but only stated that the proposed rule would not negatively impact health and well-being. The commenter requests that the Office of Management and Budget (OMB) look into this issue.

Response: The Department disagrees with commenters who suggest the proposed rule preempts State law by removing the requirement for abortion counseling and referral. This regulation only impacts the Title X program and has no impact on State laws that may, in other venues or circumstances, require State or local entities to counsel and/or refer for abortion. And to the extent that any State laws requiring referral for abortion cannot be carried out in a Title X project, it is due to Congress's restriction on the use of Title X funds in projects where abortion is a method of family planning.

The Department also disagrees with comments suggesting that federalism requires the Department to permit Title X projects to provide directive counseling and information about abortion, or referrals for abortion. As the Supreme Court held in *Rust* v. *Sullivan,* the federal government is not required to fund Title X projects that promote or refer for abortion. 500 U.S. at 193–94. Regardless of the status of State laws that some commenters say require the provision of directive counseling, information, or referrals for abortion, neither the principle of federalism nor the Constitution requires the federal government to fund Title X programs or projects—or any other program—that include directive counseling, information, or referrals for abortion as a method of family planning. And the Department believes it would be inconsistent with restrictions on the Title X program to allow (or require) Title X projects to provide directive counseling about abortion. The Department has determined that the final rule will not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The changes in the rule represent the Federal Government regulating its own program.

The Department disagrees with comments that suggest the inclusion of a federalism impact statement in the 2016 Title X regulation demands the same for this rule. The 2016 regulation was a regulatory change to the status quo of the 2000 regulations that limited the ability of states and other grantees to choose their own subrecipients; the Department specifically stated that its reason for issuing the rule was to respond to new approaches to competing or distributing Title X funds that were being employed by several States. As a result, the 2016 regulation had a federalism impact. This final rule, however, removes a provision that Congress has already legislatively repealed through the Congressional Review Act. That regulatory provision was nullified as a matter of law when the President signed the repeal. This rule simply conforms the text of the Title X regulations to what Congress has already done. Consequently, there is no federalism impact of the removal of this provision.

Additionally, States are free to apply or not apply for Title X funding and so are only required to comply with regulations in this Federal program if they decide to apply for a grant under the discretionary Title X program and, thereby, voluntarily agree to follow the statutory program integrity provisions, the regulation provisions, and those requirements communicated in the funding announcement. Should they agree that the Title X program is a good fit for their State government

application, this regulation establishes the program's core requirements to maintain statutory program integrity, but States (or other grantees) have the freedom to implement their own programs, select their own subrecipients, establish their own referral networks, and test approaches within this framework to identify the most effective and innovative means to serve Title X patients in their States.

The Department disagrees with comments suggesting that State and local entities will incur additional costs to provide services that were once part of Title X, but are no longer permitted. Commenters fail to provide convincing evidence of these costs and also fail to provide evidence that there will be reduced access to Title X services as a result of this rule. Accordingly, the Department concludes that the final rule does not contain policies that have federalism implications, as defined in Executive Order 13132 and, consequently, a federalism summary impact statement is not required.

5. Summary of the Final Rule

This final rule amends the regulations governing the Title X program to ensure programmatic compliance with statutory program integrity provisions. Specifically, the rule:

(1) Aligns the regulation with the statutory requirements and purpose of the Title X program, the appropriations provisos and riders addressing the Title X program, and other obligations and requirements established under other Federal law;

(2) Expands the scope of enforcement and auditing mechanisms available to the Department to enforce such program requirements; and

(3) Requires individuals and entities covered by this proposed rule to adhere to certain procedural and administrative requirements that aim to improve client care and increase transparency.

The Department evaluated the effects of this rule over 2019–2023. As a result of comments, it has increased estimated costs. Costs are estimated to be $69.2 million in 2019 and $14.8 million in subsequent years. Present value costs of $110.4 million and annualized costs of $26.4 million are estimated using a 3% discount rate; present value costs of $91.1 million and annualized costs of $27.2 million are estimated using a 7% discount rate. The quantified and non-quantified benefits and costs are summarized in Table 1.

TABLE 1—ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL PROPOSED CHANGES

	Present value over 5 years by discount rate (Millions of 2016 dollars)		Annualized value over 5 years by discount rate (Millions of 2016 dollars)	
	3 Percent	7 Percent	3 Percent	7 Percent
Benefits:				
Quantified Benefits	0	0	0	0
Non-quantified Benefits (see below):				
Program integrity of Title X, especially with respect to ensuring that projects and providers do not fund, support, or promote abortion as a method of family planning. Enhanced compliance with statutory requirements and appropriations riders and provisos. Expanded number of entities interested in participating in Title X, including by the removal of abortion counseling and referral requirements that potentially violate federal health care conscience protections. Enhanced patient service and care.				
Costs:				
Quantified Costs	110.4	91.1	26.4	27.2
Non-quantified Costs:				
None				

B. Analysis of Economic Impacts

1. Need for Regulatory Action

This final rule addresses two categories of problems:

(1) Insufficient compliance with the statutory program integrity provisions and the purpose and goals of the Title X program (especially those related to section 1008), the appropriations provisos and riders addressing the Title X program, and other obligations and requirements established under other Federal law; and

(2) Lack of transparency regarding the provision of services (with respect to both the identity of the providers and the services being provided by such entities). Each of the issues fall into one or more of these categories.

While the 2000 regulations state that Title X projects must not provide abortion as a method of family planning, they do not provide sufficient guidance to ensure that Title X projects comply with section 1008 by not encouraging or promoting abortion as a method of family planning. Limiting section 1008's prohibition to only ''direct'' facilitation of abortion is not consistent with the best reading of that provision, which was intended to ensure that Title X funds are also not used to encourage or promote abortion. For example, the 2000 regulations:

- Mandate that providers provide counseling on and referral for abortion, if requested by the client;
- Permit shared locations, facilities, personnel, file systems, phone numbers, and websites between Title X clinics and abortion clinics, creating confusion regarding the scope of Title X services and whether the Federal government is funding abortion services; and
- Permit a fungibility of assets that can be used to free funds and build infrastructure for abortion services, including physical space, health information technology systems, community recruitment, and bulk purchase of contraceptives and other clinic supplies.

The lack of clear operational guidance on the abortion restriction in section 1008 has created confusion as to what activities are proscribed by section 1008. With abortions increasingly performed at nonspecialized clinics primarily serving contraceptive and family planning clients, it is critical that the Department ensure that Federal funds are not directly or indirectly supporting, encouraging, or promoting abortion as a method of family planning and that there is a clear demarcation between Title X services and abortion-related services for which Title X funds cannot be used.

The 2000 regulations suffer from additional deficiencies. They are inconsistent with the conscience

protections embodied in the Church, Coats-Snowe, and Weldon Amendments; do not address the statutory requirement that Title X projects encourage family participation in minors' decisions to seek family planning services; do not address the statutory requirement that Title X projects provide counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities; do not expressly address the obligation of Title X grantees and subrecipients to comply with State sexual abuse reporting or notification requirements; and do not expressly prohibit the use of Title X funds to encourage, promote, or advocate for abortion, to support any legislative proposal that encourages abortion, or to support or oppose any candidate for public office. In addition, the 2000 regulations do not communicate that Title X providers should either offer comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site. And the 2000 regulations fail to require grantees to provide the Department sufficient information about the subrecipients with which they (or their subrecipients) contract or other partners to whom Title X funds may flow, thus hindering OPA from exercising appropriate oversight of the activities of its program and project subrecipients.

This final rule addresses each of the foregoing problems. First, to assist the Department in ensuring compliance with, and enforcement of, the section 1008 prohibition, the final rule will prohibit family planning projects from using Title X funds to encourage, promote, provide, refer for, or advocate for abortion as a method of family planning; require assurances of compliance; eliminate the requirement that Title X projects provide abortion counseling and referral; require physical and financial separation of Title X activities from those which are prohibited under section 1008; and provide clarification on the appropriate use of funds in regard to the building of infrastructure.

To assist the Department in ensuring compliance with, and enforcement of, appropriations provisos and riders addressing the Title X program, the final rule also reiterates the voluntary, non-coercive nature of Title X services; requires Title X facilities to encourage family participation in a minor's decision to seek family planning services; requires Title X facilities to provide minors with counseling on how to resist attempts to coerce them into engaging in sexual activities; prohibits the use of Title X funds for any activity that in any way tends to promote public support or opposition to any legislative proposal or candidate for office; clarifies the duty of projects to comply with State and local laws requiring notification and reporting of criminal sexual exploitation; explains that confidentiality of information may not be used as a rationale for noncompliance with such notification or reporting laws; and requires assurances of compliance and maintenance of records.

To assist the Department in ensuring compliance with conscience protections embodied in the Church, Coats-Snowe, and Weldon Amendments, the final rule eliminates the requirement that Title X projects provide abortion counseling and referral. These changes will also add clarity to extant conscience protections, making it easier for entities to participate who may have felt unable to do so in the past. In addition, though already permitted in the 2000 regulations, the final rule clarifies that participating entities within a project may offer only a single method or a limited number of methods as components of a Title X family planning project, so long as the overall project provides a broad range of acceptable and effective family planning methods and services throughout the service area.

Second, to ensure that the Title X program places an adequate emphasis on holistic family planning services that recognize the need for linkages with comprehensive primary health care providers, the final rule clarifies the definition of family planning; provides for the referral of pregnant patients for appropriate prenatal services; encourages the provision of comprehensive primary health services onsite or through a robust referral linkage; and updates the application review criteria, including to expand provision of family planning service in under- and un-served areas and populations.

Third, to ensure transparency regarding the provision of services, the final rule requires additional information from applicants and grantees regarding subrecipients, requires a clear explanation of how grantees ensure adequate oversight and accountability for compliance and quality outcomes among subrecipients and requires each project supported under Title X to fully account for, and justify, charges against the Title X grant. The Department believes these changes will ensure that OPA has the information necessary to determine whether Title X projects, grantees, and subrecipients are complying with the statutory provisions of the program. Title X grantees and subrecipients must comply with the Federal laws that are the subject of this proposed rulemaking. In addition to conducting outreach and providing technical assistance, OPA has the authority to initiate compliance reviews and take appropriate action to assure compliance with the provisions in this final rule.

2. Affected Entities

This rule would affect the operations of entities which receive Title X grants or are subrecipients of such entities at some point in time. According to the 2016 Family Planning Annual Report (FPAR), there were 91 Title X grantees and 1,117 Title X subrecipients in 2016.[130] These entities operated at 3,898 service sites, and provided services to 4,007,552 people.[131] For purposes of this analysis, the Department assumes that these numbers will remain the same across time. Title X services were delivered by 3,550 clinical services provider full-time equivalent employees (FTEs), which include 780 physician FTEs, 258 registered nurse FTEs, and 2,512 combined FTEs from physician's assistants (PAs), nurse practitioners (NPs), and certified nurse midwives (CNMs).[132] These FTEs are associated with 1,403 Title X family planning encounters per FTE, for 5.0 million total Title X family planning encounters across these providers in 2016.[133] Title X services are also delivered by other types of service providers, who were involved with 1.7 million Title X family planning encounters in 2016.[134] Providers in these categories include registered nurses, public health nurses, licensed vocational or licensed practical nurses, certified nurse assistants, health educators, social workers, and clinic aides. The Department assumes that there are 1,403 encounters per FTE for individuals in these categories, which implies approximately 1,219 FTEs in this category in 2016.[135] To convert FTEs reported in the FPAR to the number of individuals in these categories, the Department assumes that each individual works an average of between 0.5 FTEs and 1.0 FTEs delivering Title X services, with 0.75 FTEs as its central estimate, uniformly

[130] Fowler et al., *Family Planning Annual Report: 2016 National Summary* 7 (Aug. 2017), *https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf.*

[131] *Id.* at 8.

[132] *Id.* at 49–51.

[133] *Id.* at 51.

[134] *Id.* at 24.

[135] *Id.* at 49.

across occupation categories. This implies that there are approximately 4,733 clinical service providers and 1,625 other service providers associated with the provision of Title X family planning services. The Department will use these estimates as its estimate of service providers affected by this rule.

The Department estimates the hourly wages of individuals affected by this proposed rule using information on hourly wages in the May 2016 National Occupational Employment and Wage Estimates provided by the U.S. Bureau of Labor Statistics [136] and salaries from the U.S. Office of Personal Management.[137] It uses the salary of registered nurses as a proxy for ''other clinical service providers'' and ''other types of service providers'' described above. In FPAR, PAs, NPs, and CNMs are not distinguished. Since wages in these three categories are very similar, the Department uses the average wage across this group when discussing impacts affecting the group. The Department uses the wages of Medical and Health Services Managers as a proxy for management staff, and the wages of Lawyers as a proxy for legal staff throughout this analysis. To value the time of potential Title X service grantees, the Department takes the average wage across all occupations in the U.S. The Department assumes that federal employees affected by the proposed changes to the Title X regulation are Step 5 within their GS-level and earn locality pay for the District of Columbia, Baltimore, and Northern Virginia. It divides annual salaries by 2,087 hours to derive hourly wages. It assumes that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200% of the wage rate. Estimated hourly rates for all relevant categories are included below.

Throughout, estimates are presented in 2016 dollars. When present value and annualized values are presented, they are discounted relative to year 2016. Finally, the Department estimates impact over five years starting in 2019. Please note that the list includes staff that the Department assumes will be impacted by the final rule and is inclusive of those positions which are included in the APP category.

[136] Bureau of Labor Statistics, *Occupational Employment and Wage Statistics,* (May 2016), *https://www.bls.gov/oes/2016/may/oesnat.htm.*

[137] Office of Personnel Management, *Salary Table 2016–DCB,* (Jan. 2016), *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DCB.pdf.*

TABLE 2—HOURLY WAGES

Physician	$101.04
Physician Assistant	49.08
Nurse Practitioner	50.30
Certified Nurse Midwife	49.23
Registered Nurse	34.70
Medical and Health Services Managers	52.58
Lawyers	67.25
Federal employees in the District of Columbia, Baltimore, and Northern Virginia (2016)	
GS–13 Step 5	50.04
GS–14 Step 5	59.13
GS–15 Step 5	69.56

3. Estimated Costs

a. Learning the Rule's Requirements

To comply with the regulatory changes proposed in this final rule, affected entities must learn the rule's requirements, review their policies in the context of these new requirements, and determine how to respond. Affected entities here would include not only existing grantees and subrecipients, but also potential grantees and subrecipients. Consistent with our view that this proposed rule would increase competition for Title X funding, the Department estimates that potential grantees and subrecipients range from between 100% and 300% of their 2016 values, with a central estimate of 200%. This implies 182 potential grantees and 2,234 potential subrecipients. The Department estimates that learning the final rule's requirements and determining how to respond would require an average of 20 hours for potential grantees and an average of 10 hours for potential subrecipients, divided evenly between managers and lawyers, in the first year following publication of the final rule. As a result, using wage information provided in Table 2, this implies costs of $3.11 million in the first year following publication of the final rule.

b. Training

Individuals involved with delivering family planning services would need to receive training on the requirements of the final rule. To convert FTEs reported in FPAR to the number of individuals who would receive training, the Department assumes that each individual works an average of between 0.5 FTEs and 1.0 FTEs delivering Title X services, with 0.75 FTEs as its central estimate. This implies that there are approximately 4,733 clinical service providers and 1,625 other service providers who will need training in order to ensure compliance with these regulations. The Department estimates that these individuals would require an average of 4 hours of training in the first year following publication of this rule. In subsequent years, it assumes that this new information would be incorporated into existing training requirements, resulting in no incremental burden. As a result, using wage information provided in Table 2, this would imply costs of $2.71 million in the first year following publication of a final rule in this rulemaking.

In addition, training materials would need to be updated to reflect changes made by this rulemaking. Training materials for Title X providers are currently developed by contract. The Department estimates that these updates would cost approximately $200,000. In addition, changes to training materials would require interaction with OPA employees in order to ensure that the materials are suitable for Title X providers. The Department estimates that this would require half of an FTE at the GS–13 level and half of an FTE at the GS–14 level. It estimates that all of these costs would be incurred in the first year following publication of the final rule. Using wage information provided in Table 2, this would imply costs of $0.43 million in the first year after publication of the final rule.

c. Assurance Submissions

Title X grantees and subrecipients face new assurance requirements because of this final rule. The Department estimates that these new requirements would require a lawyer to spend an average of 3 hours reviewing the assurances and 3 hours reviewing organizational policies and procedures or taking other actions to assess compliance, and a medical and health services manager to spend 2 hours total for the same tasks the first year of the final rule for each grantee and subrecipient. In subsequent years, the Department estimates that these new requirements would require a lawyer to spend an average of 1 hour reviewing the assurances, 3 hours reviewing organizational policies and procedures or taking other actions to assess compliance, and a medical and health services manager to spend 2 hours total for the same tasks at each grantee and subrecipient. Using wage information provided in Table 2, this would imply costs of $1.2 million in the first year following publication of the final rule, and $0.9 million in subsequent years.

d. Documentation of Compliance

Title X grantees and subrecipients need to document their compliance

with new requirements because of this final rule. First, Title X grantees are required to encourage minors to involve family in their decisions to seek family planning services. Actions taken to satisfy this requirement must be documented in a minor's medical record. The Department estimates that each occurrence would require a physician assistant to spend an average of 2 minutes to make appropriate documentation in a minor's medical records. Approximately 20% (800,000) of the 4 million Title X clients are adolescents. The Department estimates that complying with the requirement to encourage family participation will result in 75% (600,000) of adolescent patients' medical records requiring appropriate documentation. Using wage information provided in Table 2, this would imply costs of $2.0 million in each year following publication of this rule.

In addition, the rule requires Title X projects to report certain crimes in compliance with State notification laws, and to counsel minors on how to resist sexual coercion, but the Department does not include cost estimates for compliance with these provisions because grantees are already required to comply with these congressional mandates. However, while Congress encourages family participation, especially related to minors, this rule requires an additional compliance step that grantees document that they encourage family participation with each minor—and to so document this conversation in each minor's patient file.

Second, grantees must generate reports with information related to subrecipients involved in the grantee's Title X project. The Department believes that this will impose direct and indirect costs. It estimates that these new requirements would require a health services manager to spend an average of 4 hours in each year following publication of the final rule at each grantee and subrecipient. Using wage information provided in Table 2, this would imply costs of $0.5 million in each year following publication of a final rule in this rulemaking.

In addition, based on public comment, the Department also believes that these documentation requirements will result in indirect costs. In particular, it believes that affected entities may update systems to facilitate newly required documentation and reporting. It estimates that between 25% and 75% of service sites, with a central estimate of 50%, will make changes along these lines in response to these new requirements. These changes could range from very minor tweaks to existing systems to more comprehensive overhauls. The Department estimates that an average of between $1,000 and $5,000, with a central estimate of $3,000, would be incurred at these sites in the first year following publication of this proposed rule. This would imply costs of $11.69 million in the first year following publication of a final rule.

e. Monitoring and Enforcement

This final rule will result in additional monitoring of Title X grantees and subrecipients in order to ensure compliance with new regulatory and existing statutory requirements.

Some commenters contend that requiring grantees to provide information concerning their subrecipients will be burdensome because of limited funding and the magnitude of oversight required and will prohibit them from freely selecting subrecipients. Commenters contend that these requirements will be prohibitive to providing comprehensive care and continuing partnerships with referral agencies. Other commenters contend that many clinics will be forced to close as a result of the burdensome requirements and that this is evidence of a departmental agenda to discourage participation in the Title X program. Commenters request a response as to whether the Department has studied the costs to subrecipients and referral agencies associated with data collection, training and oversight. Commenters also note that other programs with comparable federal funding are not required to submit to the same requirements.

HHS does not agree with commenters who say that providing the Department with information regarding subrecipients is unduly burdensome or prohibitive, since grantees already are responsible for ensuring that all partners who receive funding as a part of the grant project are providing services that are responsive and compliant with the purposes of Title X. The Department is only requiring that compliance and appropriate service provision be documented and submitted to HHS. Grantees may relieve reporting burdens by requiring subrecipients to draft compliance reports that grantees can submit to HHS after certifying their accuracy. Commenters provided no documentation to support the assertion that such certification of subrecipient compliance would be unique among federal programs. In addition, as a result of comments, HHS is only requiring monitoring and oversight of subrecipients, not referral agencies, because only grantees and subrecipients receive Title X funds for their services. Requirements regarding referral agencies will be limited to the grantee providing information that they should already have available, such as the name of the referral agency, the services it provides, and the extent of the referral partnership. For all of these reasons, the Department does not find this objection compelling.

Similarly, the Department does not agree with the concern expressed by some commenters regarding the effect of this rule on quality and accessibility of Title X services. These commenters did not provide evidence that the rule will negatively impact the quality or accessibility of Title X services. And the Department believes that this rule will likely improve quality and accessibility for Title X services.

For example, the Department expects that honoring statutory protections of conscience in Title X may increase the number of providers in the program. If health care providers or entities know they will be protected from discrimination on the basis of conscience with respect to counseling on, or referring for, abortion, they might seek to participate in programs as a subrecipient where they may previously have been deterred from doing so under the current regulations because of concerns that they would be forced to violate their religious belief or moral conviction. This may also lead to an increase in the number of health care providers who apply and receive funding under the Title X program, thus decreasing current gaps in family planning services in certain areas of the country. For example, under the 2000 regulations, some individuals and entities may have chosen not to apply to provide Title X services because they anticipated they would be pressured to counsel or refer for abortions. One public commenter supporting finalization of the proposed rule on behalf of religiously affiliated health care organizations cited polling data and organizational comments suggesting that protecting conscience in the Title X program would prevent medical providers or students from refraining from participation in the program due to concerns about being forced to violate their consciences.[138]

[138] See comment of Jonathan Imbody (posted July 23, 2018), available at *https://www.regulations.gov/document?D=HHS-OS-2018-0008-69125* (citing a Christian Medical Association and Freedom2Care poll conducted on May 3, 2011, which found that 91 percent of physicians who practiced medicine based on the principles of their faith said they would be forced to leave medicine if coerced into violating the faith tenets and medical ethics principles that guide their practice of medicine). Freedom2Care and The Christian Medical

Similarly, a certain proportion of decisions by currently practicing health providers to leave the profession are presumably motivated by such pressure.[139] With the final rule's added emphasis on protecting rights of conscience, more individuals may enter the Title X family planning program, helping to meet that unmet need for care.

This effect may also occur at the macro scale in the health industry. For example, hospitals or other facilities that will not refer for abortion as a method of family planning may view the final rule as granting Title X participants greater freedom to provide family planning services consistent with their beliefs and may find it worthwhile to apply for Title X funds, or seek to participate in a Title X project as a subrecipient, in order to serve more people or new populations, or underserved communities, including urban or rural, consistent with their calling to serve the health care needs of the poor and underserved.

As a result, the rule will not impede access to care in areas with fewer providers, such as rural communities, but enhance it. Indeed, because patients may seek out health care providers that reflect their own religious beliefs or moral convictions, service delivery should be improved because opportunities for conflict may be limited and the cultural competency of providers may be increased.[140] Another way this effect may manifest itself is that, if the number of family planning providers were to remain constant, the average provider would have more highly qualified staff, because the Title X grantees and their subrecipients would be selecting from a larger pool of medical and health professionals. Ultimately, the Department believes that this final rule will result in more Title X applicants, which will likely translate into more diverse grantees and subrecipients. In addition, the Department closely monitors the performance of the Title X program, including through the Family Planning Annual Report, which should allow the Department to quickly identify and respond to any problems in order to maintain high quality standards within the program.

The Department estimates that addressing additional monitoring and enforcement activities would require management staff for each grantee to spend an average of an additional 40 hours each year, and would require an average of an additional 10 hours for each Title X service provider each year. Finally, additional monitoring and enforcement require additional time by Federal staff. The Department estimates this would require 3 FTEs at the GS–13 level, 2 FTEs at the GS–14 level, and 2 FTEs at the GS–15 level. As a result, using wage information provided in Table 2, this would imply costs of $8.53 million every year following publication of this rule.

f. Physical Separation

As a result of this final rule, Title X providers would be required to provide Title X services at facilities that are physically separate from facilities at which abortion as a method of family planning is provided. A Congressional Research Service[141] report estimates that 10% of clinics that receive Title X funding offer abortion as a method of family planning in addition to their Title X-funded activities. In addition, Title X providers may share resources with unaffiliated entities that offer abortion as a method of family planning. As a result, the Department estimates that between 10% and 30% of service sites, with a central estimate of 20%, would need to be evaluated to determine whether they comply with the proposed physical separation requirements. Commenters contend that the Department underestimated the costs related to new physical separation requirements, but themselves did not provide sufficient data to estimate these effects across the Title X program. Commenters also provided extremely high cost estimates based on assumptions that they would have to build new facilities in order to comply with the requirements for physical separation from abortion as a method of family planning. The Department does not anticipate that entities will necessarily engage in construction of new facilities to comply with the new requirements, rather that entities will usually choose the lowest cost method to come into compliance. The Department expects that the lowest cost method will vary across covered entities depending on their circumstances, and that covered entities will make the decision which best suits their circumstances in light of the new requirements, and therefore that entities will likely choose the lowest cost method, given their circumstances. For example, Title X providers which operate multiple physically separated facilities and perform abortions may shift their abortion services, and potentially other services not financed by Title X, to distinct facilities, a change which likely entails only minor costs. Other Title X providers, with different circumstances, will have different options and therefore may have a more or less costly lowest cost method. Furthermore, as stated above, the Department estimates that between 10% and 30% of service sites, with a central estimate of 20%, would be subject to physical separation requirements, because their Title X services and abortion services are currently collocated. Accordingly, the Department believes that enforcing the physical separation requirements as interpreted through Section 1008 should have minimal effect on the majority of current Title X providers. The Department has updated quantitative estimates in response to these comments, while acknowledging that there is substantial uncertainty regarding the magnitude of these effects. The Department estimates that evaluation of sites would require an average of an additional five hours by management staff at each of these affected service sites in the first year following publication of the final rule. Similarly, it estimates that this evaluation would affect between 10% and 30% of grantees, with a central estimate of 20%. The Department estimates that this would require an average of an additional forty hours, divided evenly between lawyers and management staff, for each affected grantee, in the first year following publication of a final rule. It estimates that these evaluations would determine that between 10% and 20% of service sites, with a central estimate of 15%, do not comply with physical separation requirements. At each of these service sites, the Department estimates that an average of between $20,000 and

Association, *National Poll Shows Majority Support Healthcare Conscience Rights, Conscience Law* (May 3, 2011), *https://docs.wixstatic.com/ugd/809e70_7ddb46110dde46cb961ef3a678d7e41c.pdf.*

[139] The Christian Medical Association and Freedom2Care poll of May 3, 2011, found that 82% of medical professionals ''said it was either 'very' or 'somewhat' likely that they personally would limit the scope of their practice of medicine if conscience rules were not in place. This was true of 81% of medical professionals who practice in rural areas and 86% who work full-time serving poor and medically-underserved populations . . . 91% agreed, 'I would rather stop practicing medicine altogether than be forced to violate my conscience.' '') Freedom2Care and The Christian Medical Association, *National Poll Shows Majority Support Healthcare Conscience Rights, Conscience Law* (May 3, 2011).

[140] In a 2011 poll, 88% of adults said it was very or somewhat important that they share moral beliefs with their health care providers. *See* Freedom2Care and The Christian Medical Association, *National Poll Shows Majority Support Healthcare Conscience Rights, Conscience Law* (May 3, 2011).

[141] Angela Napili, *Title X (Public Health Service Act) Family Planning Program,* Congressional Research Service 22 (Aug. 31, 2017), *https://fas.org/sgp/crs/misc/RL33644.pdf.*

$40,000, with a central estimate of $30,000, would be incurred to come into compliance with physical separation requirements in the first year following publication of a final rule in this rulemaking. This estimate is an increase from an averaged estimate between $10,000 and $30,000 in the proposed rule. Using wage information provided in Table 2, this would imply costs of $36.08 million in the first year following publication of a final rule, an increase from an estimated cost of $24.38 million in the proposed rule.

The Department does not anticipate that these requirements will have a significant impact on access to services. Although some facilities may relocate in response to the new requirement, the Department does not anticipate that there will be a decrease in the overall number of facilities offering services, since it anticipates other, new entities will apply for funds, or seek to participate as subrecipients, as a result of the final rule. Further, the Department cannot calculate or anticipate future turnover in grantees. Various entities may change their decision to apply to be a grantee or sub-grantees or may change the way in which they provide services, affecting the viability of their applications. Such calculations would be purely speculative, and, thus, very difficult to forecast or quantify. Based on the Department's best estimates, it anticipates that the net impact on those seeking services from current grantees will be zero, as any redistribution of the location of facilities will mean that some seeking services will have shorter travel times and others seeking services will have longer travel times to reach a facility. Additionally, as a result of this final rule, the Department anticipates expanded competition that will engender new and/or additional grantees who will serve previously unserved or underserved areas, likely expanding coverage and patient access to services.

g. Encouraging Parental Involvement in Family Planning Services

Title X providers are already required by the Title X statute to encourage minors to involve their parents in family planning services, but this rule would ensure that actions are taken to satisfy this requirement and require such actions be documented in a minor's medical record. As noted previously, the Department estimates that complying with the requirement to document the encouragement of family participation will result in 600,000 adolescent patients' medical records requiring documentation each year. The Department estimates that an additional 0–50% of these adolescents, with a central estimate of 25%, would receive additional encouragement to involve parents each year. It estimates that this would require an average of an additional ten minutes spent by a registered nurse and ten minutes spent by the service recipient in each case. These impacts would occur each year upon publication of this final rule. Using wage information provided in Table 2, this would imply costs of $2.93 million in each year upon publication of this final rule.

The Department does not include costs associated with compliance with State reporting requirements or the requirement that minors receive counseling to avoid sexual coercion because these Congressional requirements should already be satisfied by grantees.

4. Estimated Benefits

This final rule is expected to offer benefits to taxpayers and stakeholders who want assurance that their tax dollars are being used in compliance with the requirements of the Title X program. It is also expected to increase the number of entities interested in participating in Title X as grantees or subrecipient service providers and, thereby, to increase patient access to family planning services focused on optimal health outcomes for every Title X client. Third, because of the clarifying language, as well as the new provisions within this rule, the Department expects the quality of service to improve. Finally, the rule would clarify the role of the Title X program within communities across the nation, expand and diversify the field of medical professionals who serve individuals and families, and build a better appreciation for the important services offered as a result.

a. Upholding and Preserving the Purpose and Goals of the Title X Program

As discussed throughout this rule, the statutory prohibition on the use of Title X funds in programs/projects where abortion is a method of family planning has been in existence as long as the program. This final rule is expected to provide the Department with tools to ensure compliance with those statutory requirements. It is also expected to increase transparency and assurances that taxpayer dollars are being used as Congress intended. The Title X program, too, would benefit, as the requirement of physical and financial separation and the prohibition on infrastructure building for non-Title X purposes will ensure greater accountability for the use of Federal funds and mitigate confusion about what services the Federal government supports and funds.

b. Patient/Provider Benefits and Protections

The Department expects that the final rule will have additional benefits for patients and providers. Benefits for patients are significant. First, as noted above, the new regulation will encourage Title X service providers to offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity to the Title X site. This will promote seamless care and services for patients while expanding the breadth of services available within the States, territories, and throughout the regions.

Second, the final rule will protect certain patients from coercion or further victimization. It will require Title X facilities to counsel minors on how to resist attempts to coerce them into engaging in sexual activities. Such consulting would serve to help minors resist coercion and exercise self-determination. In addition, the final rule will protect certain Title X patients from further victimization by requiring Title X grantees and subrecipients to comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking; to develop a plan for such compliance and provide adequate training for all personnel on the subject; and to maintain records identifying the age of any minor clients served, the age of their sexual partner(s) where required by law, and the reports or notifications made to appropriate State or local law enforcement or other authorities, in accordance with such laws. These provisions would protect patients, especially minor children, from further victimization, and promote the identification and bringing to justice of those who would prey on women, men, and children.

For providers, the final rule is expected to create benefits through respect for conscience. It will do so by better aligning the Title X regulations with the statutory prohibitions on discrimination against health care entities, including individual health care providers, who refuse to participate in abortion-related activity such as counseling on, and referral for, abortion. Potential grantees and subrecipients that refuse to provide abortion counseling and referrals will clearly be eligible to participate in the Title X program and to apply to provide family planning

services as grantees or subrecipients. And the expansion of provider and family planning options would have salutary benefits for patients, including for patients who seek providers who share their religious beliefs or moral convictions.

As the Department has stated with regard to other conscience protection actions, open communication in the doctor-patient relationship would foster better over-all care for patients. While the benefit of open and honest communication between a patient and her doctor is difficult to quantify, one study showed that even ''the quality of communication [between the physician and patient] affects outcomes . . . [and] influences how often, and if at all, a patient would return to that same physician.'' [142] Facilitating open communication between providers and their patients helps to eliminate barriers to care. Because positions of conscience are often grounded in religious influence, ''[d]enying the aspect of spirituality and religion for some patients can act as a barrier. These influences can greatly affect the well-being of people. These influences were reported to be an essential element in the lives of certain migrant women which enabled them to face life with a sense of equality.'' [143] It is important for patients seeking care to feel assured that their faith, and the principles of conscience grounded in their faith, would be honored, especially in the area of family planning. This would ensure that patients with such religious beliefs or moral convictions feel they are being treated fairly and that their religious beliefs or moral convictions are respected.[144]

C. Analysis of Regulatory Alternatives

The Department considered a variety of options to ensure that it is clear to grantees, the general public, and patients who depend upon Title X services, that Title X programs do not fund, support, or promote abortion as a method of family planning. Specifically, the Department considered:

(1) Maintaining the status quo, where only line-item, pro-rated financial separation from activities that treat abortion as a method of family planning is required. However, such financial accounting separation leaves too much ambiguity surrounding abortion activities that may be a part of the overall services of the organization or facility, although not a part of Title X-funded family planning services. The Department considered utilizing programmatic guidance and funding opportunity announcements (FOAs, also known as notices of funding opportunities) to address that problem, but such actions would not be able to fix the requirement that Title X providers provide counseling on, and referral for, abortion upon request, a requirement inconsistent with federal conscience laws, and at least in terms of abortion referrals, is also inconsistent with section 1008 and that could be discouraging to potential grantees and subrecipients that refuse to counsel on, or provide referrals for, abortion. The maintenance of this requirement, as noted above, is potentially inconsistent with the Coats-Snowe Amendment and the Weldon Amendment. Moreover, part 59 as it currently exists, affords no mechanisms by which the Department would be able to verify whether grantees and their subrecipients are complying with the statutory program integrity, education, and reporting requirements. In addition, the Department would still be required to use application review criteria that the Department now believes fail to ensure that applicants comply with the statutory requirements of the Title X program. As detailed earlier, application review criteria must serve as a meaningful instrument to assess the quality of the applicant and the application. While the Department had discretion under the 2000 regulations to strengthen the selection criteria through FOA requirements, such an approach does not give the public notice of the long term commitment of the program.

(2) Requiring signage, brochures or separate staff and examination rooms within the same physical space to delineate a separation between Title X and abortion-related services. The Department considered that this less restrictive option might serve the same goal as physical separation in erasing, or mitigating, the current confusion between Title X and abortion-related services. But the Department determined that a shared reception area with materials available on both Title X family planning services and abortion-related services would continue the confusion, rather than mitigate it. Signage is often not read, and the segregation of staff or staff responsibilities within the same reception area likely would not provide sufficient distinction to end confusion. If the same physical space provides both Title X and abortion-related services, signs and separate receptionists may only diminish, but not eliminate, the public perception and confusion. Different examination rooms would likely have little impact because patients would be unaware that the purpose of a suite of examination rooms differs by funding stream, if the entrance and reception area is shared in common. The optics and practical operation of two distinct services within a single collocated space are difficult, if not impossible to overcome.

Commenters contend that the Department neglected to fully address the economic impact of proposed regulatory provisions, maintain that there are more cost-effective alternatives, and present three regulatory alternatives that would not substantively change the status quo and which were not considered in the analysis: (1) Provide exemptions to those with objections to providing information about abortion; (2) improve public education efforts, so the public understands Title X funds cannot be used for abortion; and (3) permit longer time frames between finalization of, and required compliance to, the final rule in order to lower costs associated with implementation.

The Department appreciates these suggestions, but does not accept these as meaningful alternatives to the changes proposed by the rule. While cost is an important consideration in any rulemaking, compliance with statutory program integrity provisions is of greater importance and none of the alternatives suggested by commenters guarantees such program integrity. The first alternative, the provision of exemptions to those who object to providing information concerning abortion, is unnecessary with the elimination of the requirement for abortion counseling and referral. Also, the Department's approach obviates the need for a burdensome process, involving the expenditure of additional time and resources by both the provider and the federal government associated with proposing, processing, and investigating each request for exemption. The elimination of the requirement for abortion counseling and referral, coupled with the regulatory permission for nondirective pregnancy counseling, achieves the same objective without the need for such a burdensome process. In addition, the mere existence of the requirements—even with a process to apply for exemptions—may serve to discourage organizations with religious or moral objections to

[142] Fallon E. Chipidza, F. E. *et al.,* Impact of the Doctor-Patient Relationship, *The Primary Care Companion for CNS Disorders* 17(5) (Oct. 22, 2015), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4732308.*

[143] Scheppers, E. *et al.,* Potential Barriers to the Use of Health Services Among Ethnic Minorities: A Review, *Family Practice* (23):325, 343 (June 1, 2006), *https://academic.oup.com/fampra/article/23/3/325/475515.*

[144] *Id.*

counseling on, or referring for, abortion from applying. Moreover, that alternative does not address the fact that the Department believes that the current requirement to provide abortion referrals upon request is inconsistent with PHS Act § 1008's prohibition on funding projects where abortion is a method of family planning. Second, the Department agrees that educational efforts to help the general public understand the services provided by Title X would be beneficial, but this alternative does not negate the need for clear and understandable separation between Title X services and abortion services at the clinic level. Physical separation assists with statutory compliance, in addition to improving public perception, by ensuring that both intentional and unintentional comingling of resources, activities, and services do not take place in ways that are exacerbated when both services are housed in the same space. Finally, the Department considered longer implementation periods and has updated and extended transition periods and compliance dates for the provisions of this final rule, in response to comments, but the Department is not convinced that extending the time period for compliance with the final rule in any way decreases the overall cost.

The Department, therefore, concludes that no other alternative would adequately address the two categories of problems it seeks to address: (1) Insufficient compliance with the statutory requirements and the purpose and goals of the Title X program (especially those related to section 1008), the appropriations provisos and riders addressing the Title X program, and other obligations and requirements established under other Federal laws; and (2) lack of transparency regarding the provision of Title X family planning services.

Thus, for these reasons and other stated reasons for our decision to propose both physical and financial separation, the Department determines that all of these options would be insufficient to ensure statutory compliance and clarity regarding such compliance.

D. Executive Order 13771

Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule is considered an Executive Order 13771 regulatory action. The Department estimates that this rule generates $15.0 million in annualized costs at a 7% discount rate, discounted relative to fiscal year 2016, over a perpetual time horizon.

E. Regulatory Flexibility Analysis

As discussed above, the RFA requires agencies that issue a regulation to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. The Department considers a rule to have a significant economic impact on a substantial number of small entities if at least 5% of small entities experience an impact of more than 3% of revenue.

In the public comments, some commenters contend that implementing the new requirements within the first year after publication of the final rule will require transitioning to electronic health records, allocating staff to perform additional documentation, recruiting new staff/consultants, engaging legal support, and allocating training time (requiring facility closure). Commenters argue that these changes would incur costs much higher than the Department's estimated cost to implement the new requirements. Commenters express concern that these requirements will result in decreased provider participation in the Title X program, reducing services for the communities they serve.

In most cases, the Department does not find these comments compelling, since commenters do not provide sufficient detail and explanation. The Department accordingly does not find comments that predicted a large impact more reliable than the estimates set forth in the proposed rule. But the Department made some amendments to this final rule, particularly with respect to extending compliance dates and clarifying what requirements fall under each date of compliance. These amendments are described in other parts of the final rule and those germane to the RIA are detailed throughout this section.

The Department calculates the costs of the changes per service site over 2019–2023. The estimated average annualized cost of the final rule per service site is approximately $6,761 using a 3% discount rate, accounting for comments received. This represents an increase from $5,423 in the proposed rule. The Department notes that this figure includes all costs and that relatively large entities are likely to experience proportionally higher costs. The U.S. Small Business Administration establishes size standards that define a small entity. According to these standards, family planning centers with revenues below $11.0 million are considered small entities. Since the estimated costs of the final rule would be a small fraction of the standard by which a family planning center entity is considered a small entity, the Department anticipates that this final rule will not have a significant economic impact on a substantial number of small entities.

F. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998), requires Federal departments and agencies to determine whether a policy or regulation could affect family well-being.[145]

Agencies must assess whether the regulatory action: (1) Impacts the stability or safety of the family, particularly in terms of marital commitment; (2) impacts the authority of parents in the education, nurture, and supervision of their children; (3) helps the family perform its functions; (4) affects disposable income or poverty of families and children; (5) if the regulatory action financially impacts families, are justified; (6) may be carried out by State or local government or by the family; and (7) establishes a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society.[146] If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law.

Some commenters contend that the proposed rule fails to address the impact of unplanned births on families, arguing that unplanned births are a known factor in familial instability and dysfunction, decreased disposable income, and decreased relationship satisfaction. Commenters contend that the Department has incorrectly concluded that the proposed rule will not pose negative effects to family well-being, and noted a lack of evidence and/or justification for this conclusion. Commenters contend that increased

[145] This section discusses the assessment required in Executive Order 12606, The Family, which was revoked on April 21, 1997. Office of Management and Budget, Memorandum from Jacob Lew, Dir., To Heads of Executive Departments, Agencies, & Independent Establishments Assessment of Federal Regulations and Policies on Families (Jan. 26, 1999), *https://www.fws.gov/policy/library/rglew.pdf.*

[146] Treasury and General Government Appropriations Act, 1999, Public Law 105–277, sec. 654, 112 Stat. 2681, 2681–528 to 2681–530 (1998).

unintended pregnancies decrease Quality Adjusted Life Years (QALYs), and therefore the proposed rule would result in increased costs. Commenters contend that access to contraceptives has several benefits including the pursuit of higher education and increased earning power for unmarried women, leading to more enduring relationships in the future; and enabling couples to plan the number of children in their family, increasing parents' ability to invest in their children, and in turn improving children's development and ability to succeed in school.

The Department does not change from its opinion that the action taken in this final rule cannot be carried out by State or local government or by the family because the rule pertains to the enforcement of certain Federal laws and the administration of a Federal program. While the Department agrees that family planning is important, it does not agree that the final rule will negatively impact access to family planning. On the contrary, more patients could have access to services because of changes to the program. Commenters offer no compelling evidence that this rule will increase unintended pregnancies or decrease access to contraception.

Other commenters note that the Department previously has supported legislation that increases access to family planning care and provides necessary referrals. Commenters contend that the Department has supported the personal agency of families and individuals over Federal involvement in family activities in the past. Commenters contend that the Department should be required to explain its change in position.

The Department is perplexed by these comments, since the Department supports increased access to family planning services, promotes informed care for patients, and encourages family participation in family planning decisions. The final rule is designed to increase access to family planning and referrals to maintain the health of the patient. In fact, providing health care services to patients is of such importance to the Department that it encourages grantees to either provide comprehensive health services or maintain a close relationship with those who do. The Department therefore rejects the premise of this set of comments and concludes that it is not necessary to prepare a Family Policymaking Assessment.

The Secretary certifies that this final rule has been assessed in accordance with section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998), and will not negatively affect family well-being.

G. Paperwork Reduction Act

This final rule contains information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 3. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA), the Department solicited comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The Department solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA. The collections of information required by the final rule relate to § 59.2 (Definitions), § 59.5 (What requirements must be met by a family planning project?), § 59.7 (What criteria would the Department of Health and Human Services use to decide which family planning services projects to fund and in what amounts?), § 59.13 (Standards of compliance with prohibition on abortion), § 59.17 (Compliance with reporting requirements), and § 59.18 (Appropriate use of funds).

Section 59.2 would apply to situations where an unemancipated minor wishes to receive services on a confidential basis and be considered on the basis of her/his own resources, as would § 59.5(a)(14). In such cases, the Title X provider would be required to document in the minor's medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services. This documentation requirement would not apply if the Title X provider (1) believes that the minor is a victim of child abuse or incest and (2) has, consistent with applicable State or local law, reported the situation to the relevant authorities. The reporting requirement must be documented in the medical record.

Section 59.5 requires Title X providers to report, in grant applications and in all required reports, information regarding subrecipients and referral agencies and individuals, including a detailed description of the extent of collaboration and a clear explanation of how the grantee will ensure adequate oversight and accountability; and to maintain records with respect to minors on the specific actions taken to encourage family participation (or the reason why such family participation was not encouraged).

Section 59.7 requires Title X grant applicants to describe, within their applications, their affirmative compliance with each provision of the regulations governing the Title X program.

Section 59.13 requires Title X grantees to provide assurance satisfactory to the Secretary that, as a Title X grantee, it does not provide abortion and does not include abortion as a method of family planning. This assurance will include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with § 59.13 and each of the requirements in § 59.14 through § 59.16.

Section 59.17 requires Title X grantees to provide appropriate documentation or other assurance satisfactory to the Secretary that it has in place and has implemented a plan to comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. It also requires Title X grantees to maintain records to demonstrate compliance with the requirements of § 59.17, and makes continuation of funding for Title X services contingent upon demonstrating to the Secretary that the criteria have been met.

Lastly, § 59.18 requires Title X grantees to give a detailed accounting of use related to grant dollars, both in their applications for funding, and within any annually required reporting, and to fully account for, and justify, charges against the Title X grant.

Burden of Response: The Department is committed to leveraging existing grant, contract, annual reporting, and other Departmental forms where possible, rather than creating additional, separate forms for grantees to sign. The Department anticipates two separate burdens of response: (1) Assurance of compliance; and (2) documentation of compliance.

The burden for the assurance of compliance is the cost of grantee and/or subrecipient staff time to (a) review

the assurance language as well as the underlying language related to stated requirements; (b) to review grantee and/or subrecipient policies and procedures or to take other actions to assess grantee and/or subrecipient compliance with the requirements to which the grantee and/or subrecipient is required to assure compliance.

The labor cost would include a lawyer spending an average of 3 hours reviewing all assurances and a medical and health service manager spending an average of one hour reviewing and signing the assurances at each grantee and subrecipient. The Department estimates the number of grantees and subrecipients at 1,208, based on 2016 number of Title X grantees and subrecipients, as represented in Title X FPAR data. The mean hourly wage (not including benefits and overhead) for these occupations is $67.25 per hour for the lawyer and $52.58 for the medical and health service manager, as noted in the table above. The labor cost is $307,000 in the first year (($67.25 × 3 + $52.58 × 1) × 1,208 grantees and subrecipients). The Department estimates that the cost, in subsequent years, would be $145,000, which would represent an annual allotment of one hour for the lawyer and one hour for the medical and health service manager (($67.25 × 1 + $52.58 × 1) × 1,208 grantees and subrecipients).

The Department estimates that all grantees and subrecipients will review their organizational policies and procedures or take other actions to self-assess compliance with applicable Title X requirements each year, spending an average of 4 hours doing so. The labor cost is a function of a lawyer spending an average of 3 hours and a medical and health service manager spending an average of one hour. The labor cost for self-assessing compliance, such as reviewing policies and procedures, is a total of $307,000 each year (($67.25 × 3 + $52.58 × 1) × 1,208 grantees and subrecipients).

The burden for the documentation of compliance is the cost of grantee and/or subrecipient staff time to (a) document in a minor's medical records actions taken to encourage the minor to involve parents in family planning services and (b) complete reports regarding information related to subrecipients, referral agencies and individuals involved in the grantee's Title X project. The Department assumes that a physician assistant would be used to document such compliance. The mean hourly wage (not including benefits and overhead) for this occupation is $49.08 per hour. The labor cost would require spending an average of 10 minutes to make appropriate documentation in a minor's medical records. Approximately 20% (800,000) of the 4 million Title X clients are adolescents. The Department estimates that complying with the requirement to encourage family participation will result in 75% (600,000) of adolescent patients' medical records requiring appropriate documentation. The labor cost will be $982,000 each year ($49.08 per hour × 2 minutes × 600,000 adolescents).

The labor cost would also include a medical and health services manager spending an average of four hours each year to complete reports regarding information related to subrecipients involved in the grantee's Title X project at each grantee and subrecipient. The labor cost will be $254,000 each year ($52.58 per hour × 4 hours × 1,208 grantees and subrecipients).

TABLE 3—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS OR BURDEN OF RESPONSE IN YEAR ONE/SUBSEQUENT YEARS UPON PUBLICATION OF THE FINAL RULE

Regulation burden	OMB control No.	Respondents responses	Hourly rate ($)	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)
Assurance of Compliance	NEW	1,208/1,208	63.58/62.36	8/6	9,664/7,248	614,000/452,000
Documentation of Compliance	NEW	1,208/1,208	52.58/52.58	4/4	4,832/4,832	254,000/254,000
Documentation on Minor's Medical Records.	NEW	600,000/600,000	49.08/49.08	.03/.03	20,000/20,000	982,000/982,000
Total Cost						1,850,000/1,688,000

The Department asked for public comment on the information collection including what additional benefits may be cited as a result of this rule. Where warranted, changes were made in the preceding calculations of cost.

The Department has submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

List of Subjects in 42 CFR Part 59

Family planning, Grant programs—health, Grant programs—social programs, Health professions, Reporting and recordkeeping requirements, Youth, Health, Abortion, Birth control, Title X, Contraception, Natural family planning, Infertility, Fertility awareness.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR chapter I, subchapter D, part 59, as set forth below:

PART 59—GRANTS FOR FAMILY PLANNING SERVICES

■ 1. The authority citation for part 59 is revised to read as follows:

Authority: 42 U.S.C. 300 through 300a–6.

■ 2. Revise § 59.1 to read as follows:

§ 59.1 To what programs do these regulations apply?

(a) The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children. Unless otherwise specified, the requirements imposed by these regulations apply equally to grantees and subrecipients, and grantees shall require and ensure that subrecipients (and the subrecipients of subrecipients) comply with the requirements contained in these regulations pursuant to their written contracts with such subrecipients.

(b) Except for §§ 59.4, 59.8, and 59.10, the regulations of this subpart are also applicable to the execution of contracts under section 1001 of the Public Health Service Act (42 U.S.C. 300) to assist in the establishment and operation of voluntary family planning projects, and will be applied in accordance with the

applicable statutes, procedures and regulations that generally govern Federal contracts. To this extent, the use of the terms ''grant'', ''award,'', ''grantee'' and ''subrecipient'' in applicable regulations of this subpart will apply similarly to contracts, contractors and subcontractors, and the use of the term ''project'' or ''program'' will also apply to a project or program established by means of a contract.

■ 3. Amend § 59.2 by:

■ a. Adding in alphabetical order definitions for ''Advanced Practice Provider'', ''Family Planning'' and ''Grantee'';

■ b. Revising the definition of ''Low income family''; and

■ c. Adding in alphabetical order definitions for ''Program and project'', and ''Subrecipient''.

The additions and revision read as follows:

§ 59.2 Definitions.

* * * * *

Advanced Practice Provider means a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients. The term Advanced Practice Provider includes physician assistants and advanced practice registered nurses (APRN). Examples of APRNs that are an Advanced Practice Provider include certified nurse practitioner (CNP), clinical nurse specialist (CNS), certified registered nurse anesthetist (CRNA), and certified nurse-midwife (CNM).

* * * * *

Family planning means the voluntary process of identifying goals and developing a plan for the number and spacing of children and the means by which those goals may be achieved. These means include a broad range of acceptable and effective family planning methods and services, which may range from choosing not to have sex to the use of other family planning methods and services to limit or enhance the likelihood of conception (including contraceptive methods and natural family planning or other fertility awareness-based methods) and the management of infertility, including information about or referrals for adoption. Family planning services include preconception counseling, education, and general reproductive and fertility health care, in order to improve maternal and infant outcomes, and the health of women, men, and adolescents who seek family planning services, and the prevention, diagnosis, and treatment of infections and diseases which may threaten childbearing capability or the health of the individual, sexual partners, and potential future children. Family planning methods and services are never to be coercive and must always be strictly voluntary. Family planning does not include postconception care (including obstetric or prenatal care) or abortion as a method of family planning. Family planning, as supported under this subpart, should reduce the incidence of abortion.

Grantee means the entity that receives Federal financial assistance by means of a grant, and assumes legal and financial responsibility and accountability for the awarded funds, for the performance of the activities approved for funding and for reporting required information to the Office of Population Affairs.

Low income family means a family whose total income does not exceed 100% of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). The project director may find that ''Low income family'' also includes members of families whose annual income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example:

(1) Unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources, provided that the Title X provider has documented in the minor's medical records the specific actions taken by the provider to encourage the minor to involve her/his family (including her/his parents or guardian) in her/his decision to seek family planning services, except that documentation of such encouragement is not to be required if the Title X provider has documented in the medical record:

(i) That it suspects the minor to be the victim of child abuse or incest; and

(ii) That it has, consistent with, and if permitted or required by, applicable State or local law, reported the situation to the relevant authorities.

(2) For the purpose of considering payment for contraceptive services only, where a woman has health insurance coverage through an employer that does not provide the contraceptive services sought by the woman because the employer has a sincerely held religious or moral objection to providing such coverage, the project director may consider her insurance coverage status as a good reason why she is unable to pay for contraceptive services. In making that determination, the project director must also consider other circumstances affecting her ability to pay, such as her total income. The project director may, for the purpose of considering whether the woman is from a ''low income family'' or is eligible for a discount for contraceptive services on the schedule of discounts provided for in § 59.5, consider her annual income as being reduced by the total annual out-of-pocket costs of contraceptive services she uses or seeks to use. The project director may determine those costs, or estimate them at $600.

* * * * *

Program and *project* are used interchangeably and mean a plan or sequence of activities that is funded to fulfill the requirements elaborated in a Title X funding announcement; it may be comprised of, and implemented by, a single grantee or subrecipient(s), or a group of partnering providers who, under a grantee or subrecipient, deliver comprehensive family planning services that satisfy the requirements of the grant within a service area.

* * * * *

Subrecipient means any entity that provides family planning services with Title X funds under a written agreement with a grantee or another subrecipient. These entities may also be referred to as ''delegates'' or ''contract agencies.''

■ 4. Revise § 59.3 to read as follows:

§ 59.3 Who is eligible to apply for a family planning services grant or contract?

Any public or nonprofit private entity in a State may apply for a family planning grant or contract under this subpart.

■ 5. Amend § 59.5 by:

■ a. Revising paragraphs (a)(1) and (5);

■ b. Removing paragraph (a)(10)(i);

■ c. Redesignating paragraph (a)(10)(ii) as (a)(10);

■ d. Adding paragraphs (a)(12), (13), and (14); and

■ e. Revising paragraphs (b)(1) and (8).

The revisions and additions read as follows:

§ 59.5 What requirements must be met by a family planning project?

(a) * * *

(1) Provide a broad range of acceptable and effective family planning methods (including contraceptives, natural family planning or other fertility awareness-based methods) and services (including infertility services, information about or referrals for adoption, and services for adolescents). Such projects are not required to provide every acceptable and effective family planning method or service. A participating entity may offer only a single method or a limited number of methods of family planning as long as the entire project offers a broad range of such family planning methods and services.

* * * * *

(5) Not provide, promote, refer for, or support abortion as a method of family planning.

* * * * *

(12) Should offer either comprehensive primary health services onsite or have a robust referral linkage with primary health providers who are in close physical proximity, to the Title X site, in order to promote holistic health and provide seamless care.

(13) Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports:

(i) Subrecipients and agencies or individuals providing referral services by name, location, expertise and services provided or to be provided;

(ii) Detailed description of the extent of the collaboration with subrecipients, referral agencies, and any individuals providing referral services, in order to demonstrate a seamless continuum of care for clients; and

(iii) Clear explanation of how the grantee will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients.

(14) Encourage family participation in the decision to seek family planning services; and, with respect to each minor patient, ensure that the records maintained document the specific actions taken to encourage such family participation (or the specific reason why such family participation was not encouraged).

(b) * * *

(1) Provide for medical services related to family planning (including physician's consultation, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and referral to other medical facilities when medically necessary, consistent with § 59.14(a), and provide for the effective usage of contraceptive devices and practices.

* * * * *

(8) Except as provided in § 59.14(a), provide for coordination and use of referral arrangements with other providers of health care services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other federal programs.

* * * * *

■ 6. Amend § 59.7 by:

■ a. Revising paragraph (a);

■ b. Redesignating paragraphs (b) and (c) as paragraphs (d) and (e); and

■ c. Adding new paragraphs (b), and (c).

The revisions and additions read as follows:

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the establishment and operation of those projects which will, in the Department's judgment, best promote the purposes of statutory provisions applicable to the Title X program, and ensure that no Title X funds are used where abortion is a method of family planning.

(b) Any grant applications that do not clearly address how the proposal will satisfy the requirements of this regulation shall not proceed to the competitive review process, but shall be deemed ineligible for funding. The Department will explicitly summarize each requirement of the Title X regulations or include the Title X regulations in their entirety within the Funding Announcement, and shall require each applicant to describe its plans for affirmative compliance with each requirement.

(c) If the proposal is deemed compliant with this regulation, then applicants will be subject to criteria for selection within the competitive grant review process, including:

(1) The degree to which the applicant's project plan adheres to the Title X statutory purpose and goals for the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents), while meeting all of the statutory and regulatory requirements and restrictions, including that none of the funds shall be used in programs where abortion is a method of family planning.

(2) The degree to which the relative need of the applicant for Federal funds is demonstrated in the proposal, and the applicant shows capacity to make rapid and effective use of grant funds, including its ability to procure a broad range of diverse subrecipients, as applicable, in order to expand family planning services available to patients in the project area.

(3) The degree to which the applicant takes into account the number of patients, particularly low-income patients, to be served while also targeting areas that are more sparsely populated and/or places in which there are not adequate family planning services available.

(4) The extent to which family planning services are needed locally and the applicant proposes innovative ways to provide services to unserved or underserved communities.

* * * * *

■ 7. Revise § 59.11 to read as follows:

§ 59.11 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality; concern with respect to the confidentiality of information, however, may not be used as a rationale for noncompliance with laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, human trafficking, or similar reporting laws. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

■ 8. Add § 59.13 through § 59.19 to subpart A to read as follows:

Sec.

* * * * *

59.13 Standards of compliance with prohibition on abortion.
59.14 Requirements and limitations with respect to post-conception activities.
59.15 Maintenance of physical and financial separation.
59.16 Prohibition on activities that encourage, promote, or advocate for abortion.
59.17 Compliance with reporting requirements.
59.18 Appropriate use of funds.
59.19 Transition provisions; compliance.

§ 59.13 Standards of compliance with prohibition on abortion.

A project may not receive funds under this subpart unless the grantee provides assurance satisfactory to the Secretary that the project does not provide abortion and does not include abortion as a method of family planning. Such assurance must also include, at a minimum, representations (supported by documentary evidence where the Secretary requests it) as to compliance with this section and each of the requirements in §§ 59.14 through 59.16. A project supported under this subpart must comply with such requirements at all times during the project period.

§ 59.14 Requirements and limitations with respect to post-conception activities.

(a) *Prohibition on referral for abortion.* A Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take

any other affirmative action to assist a patient to secure such an abortion.

(b) *Information about prenatal care.* (1) Because Title X funds are intended only for family planning, once a client served by a Title X project is medically verified as pregnant, she shall be referred to a health care provider for medically necessary prenatal health care. The Title X provider may also choose to provide the following counseling and/or information to her:

(i) Nondirective pregnancy counseling, when provided by physicians or advanced practice providers;

(ii) A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care);

(iii) Referral to social services or adoption agencies; and/or

(iv) Information about maintaining the health of the mother and unborn child during pregnancy.

(2) In cases in which emergency care is required, the Title X project shall only be required to refer the client immediately to an appropriate provider of medical services needed to address the emergency.

(c) *Use of permitted lists or referrals to encourage abortion.* (1) A Title X project may not use the provision of any prenatal, social service, emergency medical, or other referral, of any counseling, or of any provider lists, as an indirect means of encouraging or promoting abortion as a method of family planning.

(2) The list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in paragraph (b)(1)(ii) of this section may be limited to those that do not provide abortion, or may include licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services. Neither the list nor project staff may identify which providers on the list perform abortion.

(d) *Provision of medically necessary information.* Nothing in this subpart shall be construed as prohibiting the provision of information to a project client that is medically necessary to assess the risks and benefits of different methods of contraception in the course of selecting a method, provided that the provision of such information does not promote abortion as a method of family planning.

(e) *Examples.* (1) A pregnant client of a Title X project requests prenatal health care services. Because the provision of such services is outside the scope of family planning supported by Title X, the client is referred for prenatal care and may be provided a list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care). Provision of a referral for prenatal health care is consistent with this part because prenatal care is a medically necessary service.

(2) A Title X project discovers an ectopic pregnancy in the course of conducting a physical examination of a client. Referral arrangements for emergency medical care are immediately provided. Such action complies with the requirements of paragraph (b) of this section.

(3) After receiving nondirective counseling at a Title X provider, a pregnant woman decides to have an abortion, is concerned about her safety during the procedure, and asks the Title X project to provide her with a referral to an abortion provider. The Title X project tells her that it does not refer for abortion, but provides the following: A list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), which is not presented as a referral for abortion, but as a list of comprehensive primary care and prenatal care providers that does not identify which providers perform abortion, and the project staff member does not identify such providers on the list; and information about maintaining her health and the health of her unborn child during pregnancy. Such actions comply with paragraphs (a) through (c) of this section.

(4) A pregnant woman asks the Title X project to provide her with a list of abortion providers in the area. The project tells her that it does not refer for abortion, and provides her a list that consists of hospitals and clinics and other providers, all of which provide comprehensive primary health care (including prenatal care), as well as abortion as a method of family planning. Although there are several licensed, qualified, comprehensive primary health care providers (including providers of prenatal care) in the area that do not provide abortion as a method of family planning, none of these providers is included on the list. Provision of the list is inconsistent with paragraphs (a) and (c) of this section.

(5) A pregnant woman requests information on abortion and asks the Title X project to refer her for an abortion. The counselor tells her that the project does not consider abortion a method of family planning and, therefore, does not refer for abortion. The counselor offers her nondirective pregnancy counseling, which may discuss abortion, but the counselor neither refers for, nor encourages, abortion. The counselor further tells the client that the project can help her to obtain prenatal care and necessary social services and offers her the list of licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), assistance, and information for pregnant women described in paragraph (b) of this section. None of the providers on the list provide abortions. Such actions are consistent with paragraphs (a) through (c) of this section.

(6) Title X project staff provide contraceptive counseling to a client in order to assist her in selecting a contraceptive method. In discussing oral contraceptives, the project counselor provides the client with information contained in the patient package insert accompanying a brand of oral contraceptives, referring to abortion only in the context of a discussion of the relative safety of various contraceptive methods and in no way promoting abortion as a method of family planning. The provision of this information is consistent with paragraph (d) of this section and this section generally and does not constitute an abortion referral.

§ 59.15 Maintenance of physical and financial separation.

A Title X project must be organized so that it is physically and financially separate, as determined in accordance with the review established in this section, from activities which are prohibited under section 1008 of the Act and §§ 59.13, 59.14, and 59.16 of these regulations from inclusion in the Title X program. In order to be physically and financially separate, a Title X project must have an objective integrity and independence from prohibited activities. Mere bookkeeping separation of Title X funds from other monies is not sufficient. The Secretary will determine whether such objective integrity and independence exist based on a review of facts and circumstances. Factors relevant to this determination shall include:

(a) The existence of separate, accurate accounting records;

(b) The degree of separation from facilities (*e.g.,* treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities;

(c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and

(d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.

§ 59.16 Prohibition on activities that encourage, promote, or advocate for abortion.

(a) *Prohibition on activities that encourage abortion.* (1) A Title X project may not encourage, promote or advocate abortion as a method of family planning. This restriction prohibits actions in the funded project that assist women to obtain abortions for family planning purposes or to increase the availability or accessibility of abortion for family planning purposes.

(2) Prohibited actions include the use of Title X project funds for the following:

(i) Lobbying for the passage of legislation to increase in any way the availability of abortion as a method of family planning;

(ii) Providing speakers or educators who promote the use of abortion as a method of family planning;

(iii) Attending events or conferences during which the grantee or subrecipient engages in lobbying;

(iv) Paying dues to any group that, as a more than insignificant part of its activities, advocates abortion as a method of family planning and does not separately collect and segregate funds used for lobbying purposes;

(v) Using legal action to make abortion available in any way as a method of family planning; and

(vi) Developing or disseminating in any way materials (including printed matter, audiovisual materials and web-based materials) advocating abortion as a method of family planning.

(b) *Examples.* (1) Clients at a Title X project are given brochures advertising a clinic that provides abortions, or such brochures are available in any fashion at a Title X clinic (sitting on a table or available or visible within the same space where Title X services are provided). Provision or availability of the brochure violates paragraph (a)(2)(vi) of this section.

(2) A Title X project makes an appointment for a pregnant client for an abortion for family planning purposes. The Title X project has violated paragraph (a)(1) of this section.

(3) A Title X project pays dues with project funds to a State association that, among other activities, lobbies at State and local levels for the passage of legislation to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annual budget on such activity and does not separately collect and segregate the funds for such purposes. Payment of dues to the association violates paragraph (a)(2)(iv) of this section.

(4) An organization conducts a number of activities, including operating a Title X project. The organization uses non-project funds to pay dues to an association that, among other activities, engages in lobbying to protect and expand the legal availability of abortion as a method of family planning. The association spends a significant amount of its annual budget on such activity. Payment of dues to the association by the organization does not violate paragraph (a)(2)(iv) of this section.

(5) An organization that operates a Title X project engages in lobbying to increase the legal availability of abortion as a method of family planning. The project itself engages in no such activities, and the facilities and funds of the project are kept separate from prohibited activities. The project is not in violation of paragraph (a)(2)(i) of this section.

(6) Employees of a Title X project write their legislative representatives in support of legislation seeking to expand the legal availability of abortion, in their personal capacities and using no project funds to do so. The Title X project has not violated paragraph (a)(2)(i) of this section.

(7) On her own time and at her own expense, a Title X project employee speaks before a legislative body in support of abortion as a method of family planning. The Title X project has not violated paragraph (a)(2)(i) of this section.

(8) A Title X project uses Title X funds for sex education classes in a local high school. During the course of the class, information is distributed to students that includes abortion as a method of family planning. The Title X project has violated paragraph (a)(2)(vi) of this section.

§ 59.17 Compliance with reporting requirements.

(a) Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, ''State notification laws'').

(b) A project may not receive funds under this subpart unless it provides appropriate documentation or other assurance satisfactory to the Secretary that it:

(1) Has in place and implements a plan to comply with State notification laws. Such plan shall include, at a minimum, policies and procedures that include:

(i) A summary of obligations of the project or organizations and individuals carrying out the project under State notification laws, including any obligation to inquire about or determine the age of a minor client or of a minor client's sexual partner(s);

(ii) Timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or provider with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws.

(iii) Protocols to ensure that every minor who presents for treatment is provided counseling on how to resist attempts to coerce them into engaging in sexual activities; and

(iv) Commitment to conduct a preliminary screening of any minor who presents with a sexually transmitted disease (STD), pregnancy, or any suspicion of abuse, in order to rule out victimization of a minor. Projects are permitted to diagnose, test for, and treat STDs.

(2) Maintains records to demonstrate compliance with each of the requirements set forth in paragraph (b)(1) of this section, including which:

(i) Indicate the age of minor clients;

(ii) Indicate the age of the minor client's sexual partners if such age is an element of a State notification law under which a report is required; and

(iii) Document each notification or report made pursuant to such State notification laws.

(c) Continuation of grantee or subrecipient funding for Title X services is contingent upon demonstrating to the satisfaction of the Secretary that the criteria have been met.

(d) The Secretary may review records maintained by a grantee or subrecipient for the purpose of ensuring compliance with the requirements of this section, the requirement to encourage family participation in family planning decisions, or any other section of this rule.

§ 59.18 Appropriate use of funds.

(a) Title X funds shall not be used to build infrastructure for purposes prohibited with these funds, such as support for the abortion business of a Title X grantee or subrecipient. Funds shall only be used for the purposes, and in direct implementation of, the funded project, expressly permitted by this regulation and authorized within section 1001 of the Public Health Service Act, that is, to offer family planning methods and services. Grantees must use the majority of grant funds to provide direct services to clients, and each grantee shall provide a detailed plan or accounting for the use of grant dollars, both in their applications for funding, and in any annually required reporting. Any significant change in the use of grant funds within the grant cycle shall not be undertaken without the approval of the Office of Population Affairs.

(b) Title X funds shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for office.

(c) Each project supported under Title X shall fully account for, and justify, charges against the Title X grant. The Department shall put additional protections in place to prevent possible misuse of Title X funds through misbilling or overbilling, or any other unallowable expense.

§ 59.19 Transition provisions; compliance.

(a) *Compliance date concerning physical and financial separation.* The date by which covered entitites must comply with the physical separation requirements contained in § 59.15, is March 4, 2020. The date by which covered entities must comply with the financial separation requirements contained in § 59.15 is July 2, 2019.

(b) *Compliance date concerning applications.* The date by which covered entities must comply with § 59.7 and 59.5(a)(13) (as it applies to grant applications), is the date on which competitive or continuation award applications are due, where that date occurs after July 2, 2019.

(c) *Compliance date concerning reporting, assurance, and provision of service requirements.* The date by which covered entities must comply with §§ 59.5(a)(12), 59.5(a)(13) (as it applies to all required reports), 59.5(a)(14), (b)(1) and (8), 59.13, 59.14, 59.17, and 59.18gg is July 2, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–03461 Filed 2–26–19; 4:15 pm]

BILLING CODE 5140–34–P

Reader Aids

Federal Register

Vol. 84, No. 42

Monday, March 4, 2019

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, MARCH

6953–7260 1
7261–7792 4

CFR PARTS AFFECTED DURING MARCH

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

7 CFR

210 6953
235 6953
1145 6961

Proposed Rules:

301 7304

10 CFR

Proposed Rules:

40 6979
73 6980

14 CFR

39 ..... 6962, 7261, 7264, 7266, 7269,7272
71 ..... 6965, 6966, 7274

Proposed Rules:

39 ..... 6981, 6984
71 ..... 6987, 7306, 7308

18 CFR

45 7274
46 7274

Proposed Rules:

33 7309

25 CFR

575 6967

26 CFR

1 7283

Proposed Rules:

1 6988

29 CFR

Proposed Rules:

1206 6989

32 CFR

337 6968

33 CFR

100 7285
165 ..... 6969, 6972, 7285, 7288, 7290, 7292

Proposed Rules:

100 ..... 6989, 7310
117 6992
165 6994

34 CFR

400 7294
401 7294
402 7294
403 7294
406 7294
410 7294
411 7294
413 7294
461 6974

36 CFR

Proposed Rules:

60 6996
63 6996

39 CFR

Proposed Rules:

111 7005

40 CFR

52 7299
63 7682

Proposed Rules:

52 7313
271 7010

42 CFR

59 7714

Proposed Rules:

406 7610
407 7610
422 7610
423 7610
431 7610
438 7610
457 7610
482 7610
485 7610

43 CFR

10 6975

45 CFR

Proposed Rules:

156 7610
170 7424
171 7424

47 CFR

36 6977

Proposed Rules:

64 7315

50 CFR

635 7302
679 ..... 6978, 7303

Proposed Rules:

218 7186
300 7323

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List February 26, 2019

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to *http://listserv.gsa.gov/archives/publaws-l.html*

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.