FEDERAL REGISTER

Vol. 85 Wednesday,
No. 166 August 26, 2020

Part VII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I–V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (E.O.) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department, offering for public review summarized information about forthcoming regulatory actions.

FOR FURTHER INFORMATION CONTACT: Ann C. Agnew, Executive Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; (202) 690–5627.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal government's lead agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. HHS enhances the health and well-being of Americans by promoting effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

This Agenda presents the regulatory activities that the Department expects to undertake in the foreseeable future to advance this mission. HHS has an agency-wide effort to support the Agenda's purpose of encouraging more effective public participation in the regulatory process. For example, to encourage public participation, we regularly update our regulatory web page (*http://www.HHS.gov/regulations*) which includes links to HHS rules currently open for public comment, and also provides a ''regulations toolkit'' with background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments. HHS also actively encourages meaningful public participation in its retrospective review of regulations, through a comment form on the HHS retrospective review web page (*http://www.HHS.gov/RetrospectiveReview*).

The rulemaking abstracts included in this paper issue of the **Federal Register** cover, as required by the Regulatory Flexibility Act of 1980, those prospective HHS rulemakings likely to have a significant economic impact on a substantial number of small entities. The Department's complete Regulatory Agenda is accessible online at *http://www.RegInfo.gov.*

Ann C. Agnew,

Executive Secretary to the Department.

OFFICE OF THE SECRETARY—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
80	Limiting the Effect of Exclusions Implemented Under the Social Security Act **(Rulemaking Resulting From a Section 610 Review)**.	0991–AC11

OFFICE FOR CIVIL RIGHTS—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
81	Nondiscrimination in Health and Health Education Programs or Activities	0945–AA11

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
82	21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.	0955–AA01

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
83	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
84	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
85	Medication Guide; Patient Medication Information	0910–AH68
86	Requirements for Tobacco Product Manufacturing Practice	0910–AH91
87	Nutrient Content Claims, Definition of Term: Healthy	0910–AI13
88	Revocation of Uses of Partially Hydrogenated Oils in Foods	0910–AI15

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
89	Sunlamp Products; Amendment to the Performance Standard	0910–AG30
90	Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods	0910–AH00
91	Mammography Quality Standards Act	0910–AH04
92	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products	0910–AH14
93	Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act.	0910–AH81
94	Milk and Cream Product and Yogurt Products, Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt.	0910–AI40

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
95	Acute Nicotine Toxicity Warnings for E-Liquids	0910–AH24
96	Testing Standards for Batteries and Battery Management Systems in Battery-Operated Tobacco Products	0910–AH90
97	Administrative Detention of Tobacco Products	0910–AI05

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
98	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
99	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
100	Sunscreen Drug Products For Over-The-Counter-Human Use; Final Monograph	0910–AF43
101	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
102	Required Warnings for Cigarette Packages and Advertisements	0910–AI39

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
103	Reporting of Crimes Occurring in Federally Funded Long Term Care Facilities and Enforcement Under Section 1150B of the Social Security Act (CMS–3359).	0938–AT60
104	International Pricing Index Model For Medicare Part B Drugs (CMS–5528) **(Section 610 Review)**	0938–AT91
105	FY 2021 Inpatient Rehabilitation Facility (IRF) Prospective Payment System Rate Update (CMS–1729)	0938–AU05
106	CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1734) **(Section 610 Review)**.	0938–AU10
107	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2021 Rates (CMS–1735) **(Section 610 Review)**.	0938–AU11
108	CY 2021 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1736) **(Section 610 Review)**.	0938–AU12
109	Payment Policies for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) (CMS–1738).	0938–AU17

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
110	Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas (CMS–1687) **(Section 610 Review)**.	0938–AT21
111	Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS–3347) **(Section 610 Review)**.	0938–AT36
112	Organ Procurement Organizations (OPOs) (CMS–3380) **(Section 610 Review)**	0938–AU02

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
113	CY 2020 Home Health Prospective Payment System Rate Update and Quality Reporting Requirements (CMS–1711) **(Completion of a Section 610 Review)**.	0938–AT68
114	CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1715) **(Completion of a Section 610 Review)**.	0938–AT72

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS—Continued

Sequence No.	Title	Regulation Identifier No.
115	CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1717) **(Completion of a Section 610 Review)**.	0938–AT74

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of the Secretary (OS)

Proposed Rule Stage

80. Limiting the Effect of Exclusions Implemented Under the Social Security Act (Rulemaking Resulting From a Section 610 Review)

E.O. 13771 Designation: Deregulatory.

Legal Authority: 5 U.S.C. 301; 31 U.S.C. 6101

Abstract: Exclusions implemented under the Social Security Act prevent individuals convicted of certain crimes or individuals whose health care licenses have been revoked from participating in Federal health care programs. Instead of only being barred from participating in all Federal healthcare programs, certain regulatory provisions have resulted in these type of exclusion actions being given an overly broad government-wide effect, and excluded parties have been barred from participating in all Federal procurement and non-procurement actions. However, because Social Security Act exclusions are not issued under an agency's suspension and debarment authority, they do not stop individuals from participating in all Federal procurement and non-procurement actions. For an agency to bar individuals from participating in all procurement and non-procurement activities, it must exercise its suspension and debarment authority under the Federal Acquisition Regulation or the Nonprocurement Common Rule. This rulemaking would remove the regulatory provisions at issue, in order to align the regulation with the intent of the Social Security Act and current practice.

Timetable:

Action	Date	FR Cite
NPRM	06/00/20	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Tiffani Redding, Program Analyst, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW, Washington, DC 20201, *Phone:* 202 205–4321, *Email*: *tiffani.redding@hhs.gov.*

RIN: 0991–AC11

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office for Civil Rights (OCR)

Final Rule Stage

81. Nondiscrimination in Health and Health Education Programs or Activities

E.O. 13771 Designation: Deregulatory.

Legal Authority: Sec. 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116)

Abstract: This rulemaking would finalize, with appropriate changes in response to public comments, the proposed rule implementing section 1557 of the Patient Protection and Affordable Care Act (PPACA), and conforming amendments to related HHS rules. Section 1557 of PPACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under title 1 of the PPACA.

Timetable:

Action	Date	FR Cite
NPRM	06/14/19	84 FR 27846
NPRM Comment Period End.	08/13/19	
Final Action	06/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Luben Montoya, Section Chief, Civil Rights Division, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW, Washington, DC 20201, *Phone:* 800 368–1019, *TDD Phone:* 800 537–7697, *Email*: *ocrmail@hhs.gov.*

RIN: 0945–AA11

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of the National Coordinator for Health Information Technology (ONC)

Final Rule Stage

82. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

E.O. 13771 Designation: Regulatory.

Legal Authority: Pub. L. 114–255

Abstract: The rulemaking would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric healthcare providers and reasonable and necessary activities that do not constitute information blocking. The rulemaking 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.

Timetable:

Action	Date	FR Cite
NPRM	03/04/19	84 FR 7424
NPRM Comment Period Extended.	04/23/19	84 FR 16834
NPRM Comment Period End.	05/03/19	
NPRM Comment Period Extended End.	06/03/19	
Final Action	06/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Michael Lipinski, Director, Regulatory Affairs Division, Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, 330 C Street SW, Washington, DC 20201, *Phone:* 202 690–7151.

RIN: 0955–AA01

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

83. Postmarketing Safety Reporting Requirements for Human Drug and Biological Products

E.O. 13771 Designation: Regulatory.
Legal Authority: 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 242a; 42 U.S.C. 262 and 263; 42 U.S.C. 263a; 42 U.S.C. 264; 42 U.S.C. 300aa–25; 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 360b to 360f; 21 U.S.C. 360i to 360j; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 379
Abstract: The proposed rule would amend the postmarketing safety reporting regulations for human drugs and biological products including blood and blood products in order to better align FDA requirements with guidelines of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and to update reporting requirements in light of current pharmacovigilance practice and safety information sources and enhance the quality of safety reports received by FDA. Revisions to the postmarketing safety reporting requirements were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. FDA is reproposing the proposed postmarketing requirements with revisions. Premarketing safety reporting requirements were finalized in a separate final rule published on September 29, 2010 (75 FR 59961).
Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended.	06/18/03	
NPRM Comment Period End.	07/14/03	
NPRM Comment Period Extension End.	10/14/03	
Reproposing NPRM.	12/00/20	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Jane E. Baluss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6278, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–3469, *Fax:* 301 847–8440, *Email*: *jane.baluss@fda.hhs.gov.*
RIN: 0910–AA97

84. Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products

E.O. 13771 Designation: Deregulatory.
Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371
Abstract: FDA will be proposing a rule to add the common cold indication to certain over-the-counter (OTC) antihistamine active ingredients. This proposed rule is the result of collaboration under the U.S. Canada Regulatory Cooperation Council as part of efforts to reduce unnecessary duplication and differences. This pilot exercise will help determine the feasibility of developing an ongoing mechanism for alignment in review and adoption of certain aspects of the OTC Drug Review.
Timetable:

Action	Date	FR Cite
Reopening of Administrative Record.	08/25/00	65 FR 51780
Comment Period End.	11/24/00	
NPRM (Amendment) (Common Cold).	12/00/20	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email*: *janice.adams-king@fda.hhs.gov.*
RIN: 0910–AF31

85. Medication Guide; Patient Medication Information

E.O. 13771 Designation: Regulatory.
Legal Authority: 21 U.S.C. 321 *et seq.;* 42 U.S.C. 262; 42 U.S.C. 264; 21 U.S.C. 371
Abstract: The proposed rule would amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by the FDA for human prescription drug products and certain blood products used, dispensed, or administered on an outpatient basis. The proposed rule would include requirements for Patient Medication Information development and distribution. The proposed rule would require clear and concisely written prescription drug product information presented in a consistent and easily understood format to help patients use their prescription drug products safely and effectively.
Timetable:

Action	Date	FR Cite
NPRM	11/00/20	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Chris Wheeler, Supervisory Project Manager, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 3330, Silver Spring, MD 20993, *Phone:* 301 796–0151, *Email*: *chris.wheeler@fda.hhs.gov.*
RIN: 0910–AH68

86. Requirements for Tobacco Product Manufacturing Practice

E.O. 13771 Designation: Regulatory.
Legal Authority: 21 U.S.C. 371; 21 U.S.C. 387b; 21 U.S.C. 387f
Abstract: The rule is proposing to establish tobacco product manufacturing practice (TPMP) requirements for manufacturers of finished and bulk tobacco products. This proposed rule, if finalized, would set forth requirements for the manufacture, pre-production design validation, packing, and storage of a tobacco product. This proposal would help prevent the manufacture and distribution of contaminated and otherwise nonconforming tobacco products. This proposed rule provides manufacturers with flexibility in the manner in which they comply with the proposed requirements while giving FDA the ability to enforce regulatory requirements, thus helping to assure the protection of public health.
Timetable:

Action	Date	FR Cite
NPRM	09/00/20	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Matthew Brenner, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Building 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 240 276–3904, *Email*: *ctpregulations@fda.hhs.gov.*
RIN: 0910–AH91

87. Nutrient Content Claims, Definition of Term: Healthy

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 343; 21 U.S.C. 371

Abstract: The proposed rule would update the definition for the implied nutrient content claim ''healthy'' to be consistent with current nutrition science and federal dietary guidelines. The proposed rule would revise the requirements for when the claim ''healthy'' can be voluntarily used in the labeling of human food products so that the claim reflects current science and dietary guidelines and helps consumers maintain healthy dietary practices.

Timetable:

Action	Date	FR Cite
NPRM	06/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Vincent De Jesus, Nutritionist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–830), Room 3D–031, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1774, *Fax:* 301 436–1191, *Email*: *vincent.dejesus@fda.hhs.gov.*

RIN: 0910–AI13

88. Revocation of Uses of Partially Hydrogenated Oils in Foods

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 341; 21 U.S.C. 342; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371; 21 U.S.C. 379e

Abstract: In the **Federal Register** of June 17, 2015 (80 FR 34650), we published a declaratory order announcing our final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs) are generally recognized as safe (GRAS) for any use in human food. In the **Federal Register** of May 21, 2018 (83 FR 23382), we denied a food additive petition requesting that the food additive regulations be amended to provide for the safe use of PHOs in certain food applications. We are now proposing to update our regulations to remove all mention of partially hydrogenated oils from FDA's GRAS regulations and as an optional ingredient in standards of identity. We are also proposing to revoke all prior sanctions for uses of PHOs in food.

Timetable:

Action	Date	FR Cite
NPRM	08/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ellen Anderson, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–265, 4300 River Road, College Park, MD 20740, *Phone:* 240 402–1309, *Email*: *ellen.anderson@fda.hhs.gov.*

RIN: 0910–AI15

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

89. Sunlamp Products; Amendment to the Performance Standard

E.O. 13771 Designation: Fully or Partially Exempt.

Legal Authority: 21 U.S.C. 360ii; 21 U.S.C. 360kk; 21 U.S.C. 393; 21 U.S.C. 371

Abstract: FDA is updating the performance standard for sunlamp products and ultraviolet lamps for use in these products to improve safety, reflect new scientific information, and work towards harmonization with international standards. By harmonizing with the International Electrotechnical Commission, this rule will decrease the regulatory burden on industry and allow the Agency to take advantage of the expertise of the international committees, thereby also saving resources.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79505
NPRM Comment Period End.	03/21/16	
Final Rule	09/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993, *Phone:* 301 796–5678, *Email*: *ian.ostermiller@fda.hhs.gov.*

RIN: 0910–AG30

90. Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods

E.O. 13771 Designation: Regulatory.

Legal Authority: Sec. 206 of the Food Allergen Labeling and Consumer Protection Act; 21 U.S.C. 343(a)(1); 21 U.S.C. 321(n); 21 U.S.C. 371(a)

Abstract: This final rule would establish requirements concerning ''gluten-free'' labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These additional requirements for the ''gluten-free'' labeling rule are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to fermented or hydrolyzed foods labeled as ''gluten-free.''

Timetable:

Action	Date	FR Cite
NPRM	11/18/15	80 FR 71990
NPRM Comment Period Re-opened.	01/22/16	81 FR 3751
NPRM Comment Period End.	02/16/16	
NPRM Comment Period Re-opened End.	02/22/16	
NPRM Comment Period Re-opened.	02/23/16	81 FR 8869
NPRM Comment Period Re-opened End.	04/25/16	
Final Rule	06/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Carol D'Lima, Staff Fellow, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Room 4D022, HFS 820, 5001 Campus Drive, College Park, MD 20740, *Phone:* 240 402–2371, *Fax:* 301 436–2636, *Email: carol.dlima@fda.hhs.gov.*

RIN: 0910–AH00

91. Mammography Quality Standards Act

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 360i; 21 U.S.C. 360nn; 21 U.S.C. 374(e); 42 U.S.C. 263b

Abstract: FDA is amending its regulations governing mammography. The amendments will update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA is taking this action to address changes in mammography technology and mammography processes that have occurred since the regulations were published in 1997 and to address breast density reporting to patient and healthcare providers.

Timetable:

Action	Date	FR Cite
NPRM	03/28/19	84 FR 11669
NPRM Comment Period End.	06/26/19	
Final Rule	09/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Erica Payne, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, WO 66, Room 5517, Silver Spring, MD 20993, *Phone:* 301 796–3999, *Fax:* 301 847–8145, *Email: erica.payne@fda.hhs.gov.*

RIN: 0910–AH04

92. General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 360j(e)

Abstract: This rule will apply device restrictions to sunlamp products. Sunlamp products include ultraviolet (UV) lamps and UV tanning beds and booths. The incidence of skin cancer, including melanoma, has been increasing, and a large number of skin cancer cases are attributable to the use of sunlamp products. The devices may cause about 400,000 cases of skin cancer per year, and 6,000 of which are melanoma. Beginning use of sunlamp products at young ages, as well as frequently using sunlamp products, both increases the risk of developing skin cancers and other illnesses, and sustaining other injuries. Even infrequent use, particularly at younger ages, can significantly increase these risks.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79493
NPRM Comment Period End.	03/21/16	
Final Rule	04/00/21	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993, *Phone:* 301 796–5678, *Email: ian.ostermiller@fda.hhs.gov.*

RIN: 0910–AH14

93. Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503a of the Federal Food, Drug, and Cosmetic Act

E.O. 13771 Designation: Fully or Partially Exempt.

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353a; 21 U.S.C. 355; 21 U.S.C. 371; . . .

Abstract: FDA has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs (the 503A Bulks List). The final rule will amend the 503A Bulks List by placing five additional bulk drug substances on the list. This rule will also identify 26 bulk drug substances that FDA has considered and decided not to include on the 503A Bulks List. Additional substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of a future rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	09/05/19	84 FR 46688
NPRM Comment Period End.	12/04/19	
Final Rule	12/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Rosilend Lawson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 5197, Silver Spring, MD 20993, *Phone:* 240 402–6223, *Email: rosilend.lawson@fda.hhs.gov.*

RIN: 0910–AH81

94. Milk and Cream Product and Yogurt Products, Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt

E.O. 13771 Designation: Fully or Partially Exempt.

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 336; 21 U.S.C. 341; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371(e); 21 U.S.C. 379e

Abstract: This final rule amends the standard of identity for yogurt and revokes the standards of identity for lowfat yogurt and nonfat yogurt. It modernizes the standard for yogurt to allow for technological advances, to preserve the basic nature and essential characteristics of yogurt, and to promote honesty and fair dealing in the interest of consumers. Section 701(e)(1), of the Federal Food, Drug, and Cosmetic Act requires that the amendment or repeal of the definition and standard of identity for a dairy product proceed under a formal rulemaking process. Such is consistent with the formal rulemaking provisions of the Administrative Procedures Act (5 U.S.C. 556 and 557). Although, standard practice is not to include formal rulemaking in the Unified Agenda, this rule is included to highlight the de-regulatory work in this space.

Timetable:

Action	Date	FR Cite
ANPRM	07/03/03	68 FR 39873
ANPRM Comment Period End.	10/01/03	
NPRM	01/15/09	74 FR 2443
NPRM Comment Period End.	04/29/09	
Final Rule	08/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Terri Wenger, Food Technologist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Drive, College Park, MD 20740, *Phone:* 240 402–2371, *Email: terri.wenger@fda.hhs.gov.*

RIN: 0910–AI40

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

95. Acute Nicotine Toxicity Warnings for E-Liquids

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 301 *et seq.;* 21 U.S.C. 331; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 387

Abstract: This rule would establish nicotine exposure warning requirements for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. This action is intended to protect users and non-users from accidental exposures to nicotine-containing e-liquids in tobacco products.

Timetable:

Action	Date	FR Cite
NPRM	09/00/21	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Courtney Smith, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 877 287–1426, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AH24

96. Testing Standards for Batteries and Battery Management Systems in Battery-Operated Tobacco Products

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 301 *et seq.;* 21 U.S.C. 371; 21 U.S.C. 387b; 21 U.S.C. 387g; 21 U.S.C. 387i

Abstract: This rule would propose to establish a product standard to require testing standards for batteries used in electronic nicotine delivery systems (ENDS) and require design protections including a battery management system for ENDS using batteries and protective housing for replaceable batteries. This product standard would protect the safety of users of battery-powered tobacco products and will help to streamline the FDA premarket review process, ultimately reducing the burden on both manufacturers and the Agency. The proposed rule would be applicable to tobacco products that include a non-user replaceable battery as well as products that include a user replaceable battery.

Timetable:

Action	Date	FR Cite
NPRM	06/00/21	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nathan Mease, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AH90

97. Administrative Detention of Tobacco Products

E.O. 13771 Designation: Other.

Legal Authority: 21 U.S.C. 334; 21 U.S.C. 371

Abstract: The FDA is proposing regulations to establish requirements for the administrative detention of tobacco products. This action, if finalized, would allow FDA to administratively detain tobacco products encountered during inspections that an officer or employee conducting the inspection has reason to believe are adulterated or misbranded. The intent of administrative detention is to protect public health by preventing the distribution or use of violative tobacco products until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate a regulatory action.

Timetable:

Action	Date	FR Cite
NPRM	06/00/21	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nathan Mease, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AI05

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

98. Over-the-Counter (OTC) Drug Review—External Analgesic Products

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (*i.e.,* final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Completed:

Reason	Date	FR Cite
Withdrawn	04/13/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, *Phone:* 301 796–3713, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF35

99. Over-the-Counter (OTC) Drug Review—Internal Analgesic Products

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 379e

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective, and not misbranded. After a final monograph (*i.e.,* final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses acetaminophen safety. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products.

Completed:

Reason	Date	FR Cite
Withdrawn	04/10/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF36

100. Sunscreen Drug Products for Over-the-Counter-Human-Use; Final Monograph

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 360ff–5; 21 U.S.C. 371 to 374; 21 U.S.C. 379e

Abstract: The final rule will describe the conditions of use under which OTC sunscreen products are generally recognized as safe and effective (GRASE) and not misbranded. Consistent with the Sunscreen Innovation Act, we expect that these conditions will include sunscreen dosage forms and the effectiveness of various SPF values.

Completed:

Reason	Date	FR Cite
Withdrawn	05/04/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Trang Tran, *Phone:* 240 402–7945, *Email: trang.tran@fda.hhs.gov.*

RIN: 0910–AF43

101. Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products

E.O. 13771 Designation: Regulatory.

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371; . . .

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective, and not misbranded. After a final monograph (*i.e.,* final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will propose changes to the final monograph for Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products to address safety and efficacy issues associated with pediatric cough and cold products.

Completed:

Reason	Date	FR Cite
Withdrawn	04/10/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AG12

102. Required Warnings for Cigarette Packages and Advertisements

E.O. 13771 Designation: Regulatory.

Legal Authority: 15 U.S.C. 1333; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 387c; 21 U.S.C. 387e; 21 U.S.C. 387i; Pub. L. 111–31, secs. 201 and 202, 123 Stat. 1776

Abstract: This rule will require color graphics depicting the negative health consequences of smoking to accompany textual warning statements on cigarette packages and in cigarette advertisements. As directed by Congress in the Family Smoking Prevention and Tobacco Control Act, which amends the Federal Cigarette Labeling and Advertising Act, the rule will require these new cigarette health warnings to occupy the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area of cigarette advertisements. The original rule FDA issued in 2011 was vacated by the U.S. Court of Appeals for the District of Columbia Circuit in August 2012 (*R.J. Reynolds Tobacco Co.* v. *United States Food & Drug Admin.,* 696 F.3d 1205 D.C. Cir. 2012).

Completed:

Reason	Date	FR Cite
Final Rule	03/18/20	85 FR 15638
Final Action Effective.	06/18/21	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Courtney Smith, *Phone:* 877 287–1373, *Fax:* 877 287–1426, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AI39

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

103. Reporting of Crimes Occurring in Federally Funded Long Term Care Facilities and Enforcement Under Section 1150B of the Social Security Act (CMS–3359)

E.O. 13771 Designation: Regulatory.

Legal Authority: 42 U.S.C. 1320b–25

Abstract: This proposed rule would implement federal requirements requiring specific covered individuals in long-term care facilities to report to the Secretary and law enforcement entities any reasonable suspicion that a crime has been committed against a resident of or an individual who is receiving care from such facility. It would also implement requirements of these long-term care facilities to notify such covered individuals of their reporting obligations, as well as their rights under this reporting requirement, and prohibit retaliation for making such reports. Additionally, this proposed rule would establish procedures for imposing civil money penalties and exclusion from participation in any federal health care program for violating the obligations under these requirements. The rule would also provide for hearings and appeals when those penalties and exclusions are imposed.

Timetable:

Action	Date	FR Cite
NPRM	09/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jessica Wright, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: C2–21–16, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–3838, *Email: jessica.wright@cms.hhs.gov.*

RIN: 0938–AT60

104. International Pricing Index Model for Medicare Part B Drugs (CMS–5528) (Section 610 Review)

E.O. 13771 Designation: Regulatory.

Legal Authority: Social Security Act, sec. 1115A

Abstract: This proposed rule considers testing changes to payment for certain separately payable Part B drugs and biologicals.

Timetable:

Action	Date	FR Cite
ANPRM	10/30/18	83 FR 54546
ANPRM Comment Period End.	12/31/18	
NPRM	06/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Andrew York, Social Science Research Analyst, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation, MS: WB–06–05, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–8945, *Email: andrew.york1@cms.hhs.gov.*

RIN: 0938–AT91

105. FY 2021 Inpatient Rehabilitation Facility (IRF) Prospective Payment System Rate Update (CMS–1729)

E.O. 13771 Designation: Deregulatory.

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for fiscal year 2021.

Timetable:

Action	Date	FR Cite
NPRM	04/21/20	85 FR 22065
NPRM Comment Period End.	06/15/20	
Final Action	08/00/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gwendolyn Johnson, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–06–27, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6954, *Email: gwendolyn.johnson@cms.hhs.gov.*

RIN: 0938–AU05

106. CY 2021 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1734) (Section 610 Review)

E.O. 13771 Designation: Other.
Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh
Abstract: This annual proposed rule would revise payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes would apply to services furnished beginning January 1, 2021. Additionally, this rule proposes updates to the Quality Payment Program.
Timetable:

Action	Date	FR Cite
NPRM	06/00/20	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Marge Watchorn, Deputy Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4361, *Email: marge.watchorn@cms.hhs.gov.*
RIN: 0938–AU10

107. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; The Long-Term Care Hospital Prospective Payment System; and FY 2021 Rates (CMS–1735) (Section 610 Review)

E.O. 13771 Designation: Regulatory.
Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh
Abstract: This annual final rule revises the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule implements changes arising from our continuing experience with these systems. In addition, the rule establishes new requirements or revises existing requirements for quality reporting by specific Medicare providers.
Timetable:

Action	Date	FR Cite
NPRM	05/29/20	85 FR 32460
NPRM Comment Period End.	07/10/20	
Final Action	09/00/20	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Donald Thompson, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6504, *Email: donald.thompson@cms.hhs.gov.*
RIN: 0938–AU11

108. CY 2021 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1736) (Section 610 Review)

E.O. 13771 Designation: Other.
Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh
Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The proposed rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule proposes changes to the ambulatory surgical center payment system list of services and rates. This proposed rule would also update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.
Timetable:

Action	Date	FR Cite
NPRM	06/00/20	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Marjorie Baldo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4617, *Email: marjorie.baldo@cms.hhs.gov.*
RIN: 0938–AU12

109. Payment Policies for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) (CMS–1738)

E.O. 13771 Designation: Other.
Legal Authority: 42 U.S.C. 1395l; 42 U.S.C. 1395m; 42 U.S.C. 1395u; 42 U.S.C. 1395w–3
Abstract: This rule includes proposed changes affecting Medicare payment for DMEPOS items and services.
Timetable:

Action	Date	FR Cite
NPRM	06/00/20	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Joel Kaiser, Director, Division of DMEPOS Policy, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–07–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6506, *Email: joel.kaiser@cms.hhs.gov.*
RIN: 0938–AU17

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

110. Durable Medical Equipment Fee Schedule, Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Non-Competitive Bidding Areas (CMS–1687) (Section 610 Review)

E.O. 13771 Designation: Other.
Legal Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)); Pub. L. 114–255, sec. 5004(b), 16007(a) and 16008
Abstract: This final rule follows the interim final rule that published May 11, 2018, and extended the end of the transition period from June 30, 2016, to December 31, 2016 for phasing in adjustments to the fee schedule amounts for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). In addition, the interim rule amended the regulation to resume the transition period for items furnished from August 1, 2017, through December 31, 2018. The interim rule also made technical amendments to existing regulations for DMEPOS items and services to exclude infusion drugs used with DME from the DMEPOS CBP.
Timetable:

Action	Date	FR Cite
Interim Final Rule	05/11/18	83 FR 21912
Interim Final Rule Comment Period End.	07/09/18	
Final Action to be Merged With 0938–AU17.	05/00/21	

Regulatory Flexibility Analysis Required: Yes.
Agency Contact: Alexander Ullman, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services,

Center for Medicare, MS: C5–07–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–9671, *Email: alexander.ullman@cms.hhs.gov.*

RIN: 0938–AT21

111. Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (CMS–3347) (Section 610 Review)

E.O. 13771 Designation: Deregulatory.

Legal Authority: Secs.1819 and 1919 of the Social Security Act; sec.1819(d)(4)(B) and 1919(d)(4)(B) of the Social Security Act; sec. 1819(b)(1)(A) and 1919 (b)(1)(A) of the Social Security Act

Abstract: This final rule reforms the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs that CMS has identified as unnecessary, obsolete, or excessively burdensome on facilities. This rule increases the ability of healthcare professionals to devote resources to improving resident care by eliminating or reducing requirements that impede quality care or that divert resources away from providing high-quality care.

Timetable:

Action	Date	FR Cite
NPRM	07/18/19	84 FR 34737
NPRM Comment Period End.	09/16/19	
Final Action	07/00/22	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ronisha Blackstone, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6882, *Email*: *ronisha.blackstone@cms.hhs.gov.*

RIN: 0938–AT36

112. Organ Procurement Organizations (OPOS) (CMS–3380) (Section 610 Review)

E.O. 13771 Designation: Regulatory.

Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1302

Abstract: This final rule revises the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) to increase donation rates and organ transplantation rates by replacing the current measures with new transparent, reliable, and objective measures.

Timetable:

Action	Date	FR Cite
NPRM	12/23/19	84 FR 70628
NPRM Comment Period End.	02/21/20	
Final Action	12/00/22	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Alpha–Banu Wilson, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–8687, *Email*: *alphabanu.wilson@cms.hhs.gov.*

RIN: 0938–AU02

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

113. CY 2020 Home Health Prospective Payment System Rate Update and Quality Reporting Requirements (CMS–1711) (Completion of a Section 610 Review)

E.O. 13771 Designation: Regulatory.

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395(hh)

Abstract: This annual final rule updates the payment rates under the Medicare prospective payment system for home health agencies. In addition, this rule finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model and to the Home Health Quality Reporting Program (HH QRP).

Timetable:

Action	Date	FR Cite
NPRM	07/18/19	84 FR 34598
NPRM Comment Period End.	09/09/19	
Final Action	11/08/19	84 FR 60478
Final Action Effective.	01/01/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Hillary Loeffler, Director, Division of Home Health and Hospice, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–07–22, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–0456, *Email*: *hillary.loeffler@cms.hhs.gov.*

RIN: 0938–AT68

114. CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1715) (Completion of a Section 610 Review)

E.O. 13771 Designation: Regulatory.

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule revises payment polices under the Medicare physician fee schedule, and makes other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2020. Additionally, this rule finalizes updates to the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	08/14/19	84 FR 40482
NPRM Comment Period End.	09/27/19	
Final Action	11/15/19	84 FR 62568
Final Action Effective.	01/01/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Marge Watchorn, Deputy Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4361, *Email*: *marge.watchorn@cms.hhs.gov.*

RIN: 0938–AT72

115. CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1717) (Completion of a Section 610 Review)

E.O. 13771 Designation: Regulatory.

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule revises the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule finalizes changes to the ambulatory surgical center payment system list of services and rates. This rule also updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

Action	Date	FR Cite
NPRM	08/09/19	84 FR 39398
NPRM Comment Period End.	09/27/19	
Final Action	11/12/19	84 FR 61142
Final Action Effective.	01/01/20	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Elise Barringer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–9222, *Email*: *elise.barringer@cms.hhs.gov.*

RIN: 0938–AT74

[FR Doc. 2020–16751 Filed 8–25–20; 8:45 am]

BILLING CODE 4150–03–P