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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 HEALTH AND HUMAN SERVICES

45 CFR Parts 146, 147, 148, 153, 155, and 156

[CMS-9926-P]

RIN 0938-AT37

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters; and user fees for Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal Platform (SBE-FPs). It proposes changes that would allow greater flexibility related to the duties and training requirements for the Navigator program and proposes changes that would provide greater flexibility for direct enrollment entities, while strengthening program integrity oversight over those entities. It proposes policies that are intended to reduce the costs of prescription drugs. It includes proposed changes to Exchange standards related to eligibility and enrollment; exemptions; and other related topics.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 19, 2019.

ADDRESSES: In commenting, please refer to file code CMS-9926-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-9926-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-9926-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:

Jeff Wu, (301) 492-4305, Ken Buerger, (410) 786-1190, or Abigail Walker, (410) 786-1725, for general information.

David Mlawsky, (410) 786-6851, for matters related to guaranteed renewability.

Avareena Cropper, (410) 786-3794, for matters related to sequestration.

Krutika Amin, (301) 492-5153, or Allison Yadsko, (410) 786-1740, for matters related to risk adjustment.

Krutika Amin, (301) 492-5153, for matters related to Federally-facilitated Exchange and State-based Exchange on the Federal Platform user fees.

Abigail Walker, (410) 786-1725, Alper Ozinal, (301) 492-4178, Allison Yadsko, (410) 786-1740, or Adam Shaw, (410) 786-1091, for matters related to risk adjustment data validation.

Ken Buerger, (410) 786-1190, or LeAnn Brodhead, (410) 786-3943, for matters related to the opioid crisis.

Amir Al-Kourainy, (301) 492-5210, for matters related to Navigators.

Carly Rhyne, (301) 492-4188, for matters related to special enrollment periods.

Amanda Brander, (202) 690-7892, for matters related to exemptions.

Daniel Brown, (434) 995-5886, for matters related to direct enrollment.

Rebecca Zimmermann, (301) 492-4396, for matters related to health insurance issuer drug policy, essential health benefits, and qualified health plan certification requirements.

Amy Spiridon, (301) 492-4417, for matters related to the required

contribution percentage, cost-sharing parameters and the premium adjustment percentage.

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.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

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I. Executive Summary

American Health Benefit Exchanges, or “Exchanges” are entities established under the Patient Protection and Affordable Care Act¹ (PPACA) through which qualified individuals and qualified employers can purchase health insurance coverage. Many individuals who enroll in qualified health plans (QHPs) through individual market Exchanges are eligible to receive a premium tax credit to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. The PPACA also established the risk adjustment program, which is intended to increase the workability of the PPACA regulatory changes in the individual and small group markets, both on and off Exchanges.

On January 20, 2017, the President issued an Executive Order which stated that, to the maximum extent permitted by law, the Secretary of HHS and heads of all other executive departments and agencies with authorities and responsibilities under the PPACA should exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the PPACA that would impose a fiscal burden on any state or

a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications. In this proposed rule, we are proposing, within the limitations of the current statute, to reduce fiscal and regulatory burdens across different program areas, and to provide stakeholders with greater flexibility.

Over time, issuer exits and increasing insurance rates have threatened the stability of the individual and small group market Exchanges in many geographic areas. Unfortunately, Exchange plans are now almost entirely unaffordable for people who do not qualify for PPACA’s advance payments of premium tax credits at enrollment. In the first half of 2018, 87 percent of Exchange enrollees received advance payments of the premium tax credit, with the amount covering 87 percent of the premium, on average. Sixteen percent of enrollees were enrolled in plans with zero premium after the application of premium tax credit, and another 19 percent of enrollees received a tax credit that covered at least 95 percent of the premium.²

In previous rulemaking, we established provisions and parameters to implement many PPACA requirements and programs. In this proposed rule, we propose to amend these provisions and parameters, with a focus on maintaining a stable regulatory environment to provide issuers with greater predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs and providing states with additional flexibilities, reducing unnecessary regulatory burdens on stakeholders, empowering consumers, and improving affordability.

Risk adjustment continues to be a core program in the individual and small group markets both on and off the Exchanges, and we propose recalibrated parameters for the HHS-operated risk adjustment methodology. We propose several changes related to the risk adjustment data validation program that are intended to ensure the integrity of the results of risk adjustment, and others intended to alleviate issuer burden associated with participating in risk adjustment data validation.

As we do every year in the HHS notice of benefit and payment parameters, we propose updated parameters applicable in the individual and small group markets. We propose the user fee rate for issuers participating

on Federally-facilitated Exchanges (FFE) and State-based Exchanges on the Federal platform (SBE-FPs) for 2020 to be 3.0 and 2.5 percent of premiums, respectively. These rates would be a decrease from past years, which would increase affordability for consumers. We propose to use a new premium measure to determine the rate of premium growth for purposes of calculating the premium adjustment percentage for 2020 and beyond, which is used to set the maximum annual limitation on cost sharing, the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Internal Revenue Code (the Code), and the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code. We propose to update the maximum annual limitations on cost sharing for the 2020 benefit year, including those for cost-sharing reduction plan variations.

We also propose changes to the requirements regarding Navigators to reduce burden, increase flexibility, and enable Exchanges to more easily and cost-effectively operate their programs.

We are committed to promoting a consumer-driven health care system in which consumers are empowered to select and maintain health care coverage of their choosing. To this end, we propose to expand the QHP options available to consumers on the Exchange by requiring QHP issuers that provide coverage of certain abortion services in QHPs to provide otherwise identical QHP benefit coverage that omits coverage of such abortion services in a separate QHP, to the extent permissible under applicable state law.

We also propose a number of changes in this rule that are intended to reduce the burden for consumers by making it easier to enroll in affordable coverage through the Exchange. First, we propose to provide additional flexibility to those in need of a hardship exemption, which consumers apply for now through Exchanges, by expanding the types of hardship exemptions that consumers may claim for 2018 through the tax filing process. Second, we believe consumers should have greater flexibility in how they shop for coverage, including the avenues through which they enroll in QHPs. As such, we have been working to expand opportunities for individuals to directly enroll in Exchange coverage by enrolling through the websites of certain third parties, called direct enrollment entities, rather than having to visit *HealthCare.gov*. We propose several regulatory changes to streamline the regulatory requirements applicable to

¹ The PPACA (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the PPACA, was enacted on March 30, 2010. In this proposed rule, we refer to the two statutes collectively as the “Patient Protection and Affordable Care Act” or “PPACA”.

² CMS Exchange enrollment and payment data.

these direct enrollment entities. Third, we propose to create a special enrollment period for off-Exchange enrollees who experience a decrease in household income and are determined to be eligible for advance payments of the premium tax credit (APTC) by the Exchange. This would allow enrollees to enroll in a more affordable on-Exchange product when a consumer's household income decreases mid-year.

Currently, enrollees in plans offered through a Federally-facilitated Exchange or a State-based Exchange using the Federal platform can take action to re-enroll in their current plan, can take action to select a new plan, or can take no action and be re-enrolled in their current plan. Since the program's inception, these Exchanges have maintained an automatic re-enrollment process which generally continues enrollment for current enrollees who do not notify the Exchange of eligibility changes or take action to actively select the same or different plan. In the open enrollment period for 2019 coverage, 1.8 million people in states using the Federal platform³ were automatically re-enrolled in coverage, including about 270,000 who were enrolled in a plan with zero premium after application of advance payments of the premium tax credit.⁴ Automatic re-enrollment significantly reduces issuer administrative expenses and makes enrolling in health insurance more convenient for the consumer. While allowing auto-re-enrollment was designed to be consistent with broader industry practices, this market is arguably different, since most current enrollees receive significant government subsidies, making them potentially less sensitive to premiums and premium changes. For the first half of 2018, for example, 16 percent of enrollees were enrolled in a plan with zero premiums after application of advance payments of the premium tax credit, another 19 percent of enrollees paid a premium of less than 5 percent of the total plan premium after application of advance payments of the premium tax credit, and the average subsidized enrollee received a premium tax credit covering 87 percent of the total premium cost.

The practice of automatic re-enrollment in the Exchanges gives rise to several concerns. Some consumers who are automatically re-enrolled in their current plan may be shielded from changes to their coverage, which may

result in consumers being less aware of their options from year to year. There is a concern that automatic re-enrollment eliminates an opportunity for consumers to update their coverage and premium tax credit eligibility as their personal circumstances change, potentially leading to eligibility errors, tax credit miscalculations, unrecoverable federal spending on the credits, and general consumer confusion.

We seek comment on the automatic re-enrollment processes and capabilities as well as additional policies or program measures that would reduce eligibility errors and potential government misspending for potential action in future rulemaking applicable not sooner than plan year 2021.

In addition, we believe increased transparency is a critical component of a consumer driven health care system, and are interested in ways to provide consumers with greater transparency with regards to their own health care data, QHP offerings on the FFEs, and the cost of health care services. In general, we encourage QHP issuers and Exchanges to undertake efforts to engage in consumer-friendly communication of their services to help consumers understand the value of services they would potentially obtain. We believe that when consumers have access to relevant, consumer-friendly information that is meaningful to them, they are empowered to make more informed decisions with regards to their care. This can have the effect of aligning with consumers' goals and preferences, promoting value and improving health outcomes.

Specifically, we are exploring ways to increase the interoperability of patient-mediated health care data across health care programs, including in coverage purchased through the Exchanges. We believe that providing data in an easily accessible manner through common technologies in a convenient, timely, and portable way is in the best interest of consumers and the health care system as a whole. This can prevent duplicative medical services, assist in supporting health care value through the prevention of fraud, waste, and abuse, reduce health care spending, and drive down the costs of health care for consumers. We expect to provide further information on these interoperability efforts, and an opportunity for public input, in the near future.

Additionally, in an effort to increase consumer transparency through access to information that may assist consumers in selecting a QHP offered through an Exchange and navigating

their coverage, we are exploring opportunities to expand the transparency in coverage data collection.⁵ Under section 1311(e)(3) of the PPACA, as implemented by 45 CFR 155.1040(a) and 156.220, QHP issuers must post and make available to the public, data related to transparency in coverage in plain language and submit this data to HHS, the Exchange, and the state insurance commissioner.⁶ These standards provide greater transparency for consumers and may assist in the decision-making process. This resubmission of the information collections approved under the Paperwork Reduction Act package was posted at the **Federal Register** for 60-day public comment through December 24, 2018. Separate from the PRA submission, we seek comment on ways to further implement § 156.220(d), enrollee cost-sharing transparency, where a QHP issuer must make available the amount of enrollee cost sharing under the individual's plan or coverage for the furnishing of a specific item or service by a participating provider in a timely manner upon the request of the individual. We are particularly interested in input regarding what types of data would be most useful to improving consumers' abilities to make informed health care decisions, including decisions related to their coverage.

Finally, we are interested in ways to improve consumers' access to information about health care costs. We believe that consumers would benefit from a greater understanding of what their potential out-of-pocket costs would be for various services, based on which QHP they are enrolled in and which provider they see. We believe that such a policy would promote consumers' ability to shop for covered services, and to play a more active role in their health care. In particular, we are aware that it can be difficult for consumers to anticipate their financial

⁵ CMS-10572, Transparency in Coverage Reporting by Qualified Health Plan Issuers (approved June 16, 2016).

⁶ Section 2715A of the PHS Act extends the transparency reporting provisions in section 1311(e)(3) of the PPACA to non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage and the Departments of HHS, Labor and the Treasury (the Departments) have concurrent jurisdiction over that provision. The Departments have not provided final guidance implementing any transparency reporting requirements under PHS Act section 2715A and the PRA resubmission referred to above does not relate to PHS Act section 2715A. See FAQs about Affordable Care Act Implementation (Part XXVIII). Available at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQ-Part-XXVIII-transparency-reporting-final-8-11-15.pdf>.

³ Includes Federally-facilitated Exchanges and State Exchanges that use the federal eligibility and enrollment platform.

⁴ CMS Multi-Dimensional Insurance Data Analytics System (MIDAS).

responsibility when a QHP applies coinsurance, because consumers are largely unaware of the negotiated rate until they receive an explanation of benefits document *after* the provider renders the service. We are considering different options for disclosure of cost-sharing information, recognizing that cost is a significant factor in creating greater value in health care delivery. For example, we are considering whether to require issuers to disclose a consumer's anticipated costs for particular services upon request within a certain timeframe, or whether to require issuers to disclose anticipated costs for a set number of common coverage scenarios, similar to what they must currently disclose in the Summary of Benefits and Coverage (SBC).

To increase transparency for the individual and small group markets more generally, we are proposing to expand the collection of masked enrollee-level data from the External Data Gathering Environment (EDGE) servers, and to broaden the permissible uses of such data currently submitted for purposes of risk adjustment. We believe this proposal, if finalized, would increase understanding of these markets among HHS, researchers, and the general public, and therefore contribute to greater transparency.

We seek comments on whether there are any existing regulatory barriers that stand in the way of privately led efforts at pricing transparency, and ways that we can facilitate or support increased private innovation in pricing transparency. As part of our ongoing efforts to empower consumers in their health care decisions, we also seek comment on how we can promote transparency for consumers and value-based insurance design. We seek comment on ways that we can promote the offering and take-up of High Deductible Health Plans (HDHPs) that can be paired with Health Savings Accounts (HSAs), which can serve as an effective and tax-advantageous method for certain consumers to manage their health care expenditures. We are particularly interested in comments that address ways to increase the visibility of HSA-eligible HDHPs on *HealthCare.gov*.

In furtherance of the Administration's priority to reduce prescription drug costs and to align with the President's American Patients First blueprint, we propose a series of changes to the prescription drug benefits, to the extent permitted by applicable state law. These proposals include allowing issuers to adopt mid-year formulary changes to incentivize greater enrollee use of lower-cost generic drugs; allowing issuers to not count certain cost sharing

toward the annual limitation on cost sharing if a consumer selects a brand drug when a medically appropriate generic drug is available; and allowing issuers to exclude drug manufacturer coupons from counting toward the annual limitation on cost sharing when a medically appropriate generic drug is available. We believe these proposals will support issuers' ability to lower the cost of coverage and generate cost savings while also ensuring efficient use of federal funds and sufficient coverage for people with diverse health needs.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets, including a guaranteed renewability requirement in the individual, small group, and large group markets.

Subtitles A and C of title I of the PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

Section 1302 of the PPACA provides for the establishment of an essential health benefits (EHB) package that includes coverage of EHB (as defined by the Secretary), cost-sharing limits, and actuarial value requirements. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Section 1301(a)(1)(B) of the PPACA directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the PPACA, including coverage of the services described in section 1302(b) of the PPACA, adherence to the cost-sharing limits described in section 1302(c) of the PPACA, and meeting the actuarial value (AV) levels established in section 1302(d) of the PPACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or

after January 1, 2014, extends the requirement to cover the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost sharing under the plan does not exceed the limitations described in sections 1302(c)(1) of the PPACA.

Section 1303 of the PPACA provides special rules for QHPs that offer abortion coverage in the individual market Exchanges. Under this section, QHP issuers may elect whether to provide coverage for abortion services through their QHPs offered on the Exchange. Section 1303 of the PPACA covers a variety of other requirements and provisions relating to QHP coverage of abortion services, including parameters for when federal funding is prohibited for abortion coverage, how QHPs shall ensure that no such federal funding is attributed to coverage of certain abortion services, provisions on non-preemption of certain state laws regarding abortion coverage, and provisions on non-preemption of federal conscience, nondiscrimination, and emergency services laws.

Since 1976, Congress has annually attached language, commonly known as the Hyde Amendment, to its annual Labor, Health and Human Services, Education, and Related Agencies appropriations legislation.⁷ The Hyde Amendment as currently in effect permits federal funds to be used for abortions only in the limited cases of rape, incest, or if a woman suffers from a life-threatening physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, as certified by a physician ("Hyde abortion coverage"). The Hyde Amendment prohibits the use of federal funds for abortions or abortion coverage in instances beyond those limited circumstances ("non-Hyde abortion coverage" or "abortion coverage").

Section 1311(d)(3)(B) of the PPACA permits a state, at its option, to require QHPs to cover benefits in addition to the EHB. This section also requires a state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional state-required benefits.

Section 1302(d) of the PPACA describes the various levels of coverage

⁷ The Hyde Amendment is not permanent federal law.

based on AV. Consistent with section 1302(d)(2)(A) of the PPACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the PPACA directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(b)(1)(B) of the PPACA directs that the Small Business Health Options Program assist qualified small employers in facilitating the enrollment of their employees in QHPs offered in the small group market. Sections 1312(f)(1) and (2) of the PPACA define qualified individuals and qualified employers. Under section 1312(f)(2)(B) of the PPACA, beginning in 2017, states have the option to allow issuers to offer QHPs in the large group market through an Exchange.⁸

Section 1311(d)(4)(B) of the PPACA requires an Exchange to provide for the operation of a toll-free telephone hotline to respond to requests for assistance.

Sections 1311(d)(4)(K) and 1311(i) of the PPACA direct all Exchanges to establish a Navigator program.

Section 1311(c)(6)(C) of the PPACA establishes special enrollment periods and section 1311(c)(6)(D) of the PPACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.

Section 1312(c) of the Affordable Care Act generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk pools under section 1312(c)(3) of the Affordable Care Act.

Section 1312(e) of the PPACA directs the Secretary to establish procedures under which a state may permit agents and brokers to enroll qualified individuals and qualified employers in QHPs through an Exchange and to assist individuals in applying for premium tax credits and cost-sharing reductions for QHPs sold through an Exchange.

Section 1321(a) of the PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the PPACA. Section 1321(a)(1) of the

PPACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the PPACA for, among other things, the establishment and operation of Exchanges.

Section 1311(c) of the PPACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs. Section 1311(e)(1) of the PPACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c) of the PPACA, and the Exchange determines that making the plan available through the Exchange is in the interests of individuals and employers in the state.

Sections 1313 and 1321 of the PPACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-discriminatory administration of State Exchange activities. Section 1321 of the PPACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

When operating an FFE under section 1321(c)(1) of the PPACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the PPACA to collect and spend user fees. In addition, 31 U.S.C. 9701 permits a federal agency to establish a charge for a service provided by the agency. Office of Management and Budget (OMB) Circular A–25 Revised establishes federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public.

Section 1321(d) of the PPACA provides that nothing in title I of the PPACA should be construed to preempt any state law that does not prevent the application of title I of the PPACA. Section 1311(k) of the PPACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1343 of the PPACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than average risk populations, such as those with chronic conditions, funded by payments from those that attract lower- than average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees.

Section 1402 of the PPACA provides for, among other things, reductions in cost sharing for EHB for qualified low-

and moderate-income enrollees in silver level health plans offered through the individual market Exchanges. This section also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 5000A of the Code, as added by section 1501(b) of the PPACA requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to \$0, effective for months beginning after December 31, 2018.⁹ Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals above the age of 30 qualify to enroll in catastrophic coverage under § 155.305(h).

The Protecting Affordable Coverage for Employees Act (Pub. L. 114–60, enacted on October 7, 2015) amended the definition of small employer in section 1304(b) of the PPACA and section 2791(e) of the PHS Act to mean, in connection with a group health plan for a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. It also amended these statutes to make conforming changes to the definition of large employer, and to provide that a state may treat as a small employer, for a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year.

1. Premium Stabilization Programs¹⁰

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to

⁸ If a state elects this option, the rating rules in section 2701 of the PHS Act and its implementing regulations will apply to all coverage offered in such state's large group market (except for self-insured group health plans) under section 2701(a)(5) of the PHS Act.

⁹ Public Law 115–97, 131 Stat. 2054 (2017).

¹⁰ The term premium stabilization programs refers to the risk adjustment, risk corridors, and reinsurance programs established by the PPACA. See 42 U.S.C. 18061, 18062, and 18063.

the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409). In the June 19, 2013 **Federal Register** (78 FR 37032), we proposed a modification to the HHS-operated methodology related to community rating states. In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the proposed modification to the HHS-operated methodology related to community rating states. We published a correcting amendment to the 2014 Payment Notice final rule in the November 6, 2013 **Federal Register** (78 FR 66653) to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743). In the May 27, 2014 **Federal Register** (79 FR 30240), the 2015 fiscal year sequestration rate for the risk adjustment program was announced.

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

In the December 2, 2015 **Federal Register** (80 FR 75487), we published a proposed rule outlining the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 **Federal Register** (81 FR 12203).

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining the benefit and payment parameters for the 2018 benefit

year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology, new policies around the use of external data for recalibration of our risk adjustment models, and amendments to the risk adjustment data validation process (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058).

In the November 2, 2017 **Federal Register** (82 FR 51042), we published a proposed rule outlining the benefit and payment parameters for the 2019 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology and amendments to the risk adjustment data validation process (proposed 2019 Payment Notice). We published the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 16930). We published a correction to the 2019 risk adjustment coefficients in the 2019 Payment Notice final rule in the May 11, 2018 **Federal Register** (83 FR 21925). On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level EDGE dataset.¹¹

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17220 through 17252) and in the March 8, 2016 editions of the **Federal Register** (81 FR 12204 through 12352). This final rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. This final rule permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of this final rule.¹²

¹¹ "Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients." July 27, 2018. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf>.

¹² "Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year." July 27, 2018. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf>.

In the August 10, 2018 **Federal Register** (83 FR 39644), we published a proposed rule seeking comment on adopting the 2018 benefit year risk adjustment methodology in the final rules published in the March 23, 2012 (77 FR 17219) and in the December 22, 2016 editions of the **Federal Register** (81 FR 94058). The proposed rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner. In the December 10, 2018 **Federal Register** (83 FR 63419), we issued a final rule adopting the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17219) and the December 22, 2016 (81 FR 94058) editions of the **Federal Register**. This final rule sets forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner.

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the "first Program Integrity Rule" published in the August 30, 2013 **Federal Register** (78 FR 54069) and the "second Program Integrity Rule" published in the October 30, 2013 **Federal Register** (78 FR 65045).

3. Market Rules

An interim final rule relating to the HIPAA health insurance reforms was published in the April 8, 1997 **Federal Register** (62 FR 16894). A proposed rule relating to the 2014 health insurance market rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the health insurance market rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and Beyond was published in the March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015

and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule). The 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058) provided additional guidance on guaranteed availability and guaranteed renewability. In the April 18, 2017 Market Stabilization final rule (82 FR 18346), we released further guidance related to guaranteed availability.

4. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to states on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and SHOP, eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

We established additional standards for SHOP in the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541). The provisions established in the interim final rule were finalized in the second Program Integrity Rule. We also set forth standards related to Exchange user fees in the 2014 Payment Notice. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services Under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In a final rule published in the March 27, 2012 **Federal Register** (77 FR 18309), we established the original regulatory Navigator duties and training requirements. In a final rule published in the July 17, 2013 **Federal Register** (78 FR 42823), we established standards for Navigators and non-Navigator assistance personnel in FFEs and for non-Navigator assistance personnel funded through an Exchange establishment grant. This final rule also established a certified application counselor program for Exchanges and set standards for that program. In the 2017 Payment Notice final rule, published in the March 8,

2016 **Federal Register** (81 FR 12204), we expanded Navigator duties and training requirements. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we removed the requirements that each Exchange must have at least two Navigator entities; that one of these entities must be a community and consumer-focused nonprofit group; and that each Navigator entity must maintain a physical presence in the Exchange service area.

In an interim final rule, published in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule, published in the December 22, 2016 **Federal Register** (81 FR 94058). In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we modified parameters around certain special enrollment periods.

In a final rule published in the March 27, 2012 **Federal Register** (2012 Exchange Establishment Rule), we codified the statutory provisions of section 1303 of the PPACA at § 156.280, including the accounting and notice requirements.¹³ In the February 20, 2015 **Federal Register**, we published the HHS Notice of Benefit and Payment Parameters for 2016 (2016 Payment Notice). In that final rule, we clarified these requirements and established that states and state insurance commissioners are the entities primarily responsible for implementing and enforcing the provisions in section 1303 of the PPACA related to individual market QHP coverage of non-Hyde abortion services.¹⁴ In the 2016 Payment Notice, we also established acceptable methods that a QHP offering non-Hyde abortion coverage on the Exchange may use to comply with these accounting and notice requirements. On October 6, 2017, we released a bulletin that again outlined these requirements in greater detail and set forth how they are to be enforced beginning in plan year 2018.¹⁵ On November 9, 2018, we published the Patient Protection and Affordable Care

¹³ 77 FR 18309.

¹⁴ 80 FR 10749.

¹⁵ CMS Bulletin Addressing Enforcement of Section 1303 of the Patient Protection and Affordable Care Act (October 6, 2017). Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Section-1303-Bulletin-10-6-2017-FINAL-508.pdf>.

Act; Exchange Program Integrity proposed rule in the **Federal Register** (83 FR 56015) that would require QHP issuers to issue separate bills for coverage of non-Hyde abortion, as well as noting the obligation of QHP issuers to maintain records of their compliance with the requirements of section 1303 of the PPACA and the related regulatory provisions and to make them available for audits, compliance reviews, and investigations of noncompliance.

5. Essential Health Benefits

On December 16, 2011, HHS released a bulletin¹⁶ that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. A proposed rule relating to EHBs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), we added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond.

6. Minimum Essential Coverage

In the February 1, 2013 **Federal Register** (78 FR 7348), we published a proposed rule that designates other health benefits coverage as MEC and outlines substantive and procedural requirements that other types of coverage must fulfill to be recognized as MEC. The provisions were finalized in the July 1, 2013 **Federal Register** (78 FR 39494).

In the November 26, 2014 **Federal Register** (79 FR 70674), we published a proposed rule seeking comments on whether state high risk pools should be permanently designated as MEC or whether the designation should be time-limited. In the February 27, 2015 **Federal Register** (80 FR 10750), we designated state high risk pools established on or before November 26, 2014 as MEC.

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges, including the SHOP, and the risk adjustment and risk adjustment data validation programs. We have held a number of listening sessions with

¹⁶ "Essential Health Benefits Bulletin." December 16, 2011. Available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

consumers, providers, employers, health plans, and the actuarial community to gather public input. We have solicited input from state representatives on numerous topics, particularly essential health benefits, QHP certification, Exchange establishment, and risk adjustment. We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all public input we received as we developed the policies in this proposed rule.

C. Structure of Proposed Rule

The regulations outlined in this proposed rule would be codified in 45 CFR parts 146, 147, 148, 153, 155, and 156.

The proposed changes to 45 CFR parts 146, 147, and 148 would allow issuers, beginning with plan years on or after January 1, 2020, to update their prescription drug formularies by allowing certain mid-year formulary changes, subject to applicable state law, in an effort to optimize the use of new generic drugs as they become available.

The proposed changes to 45 CFR part 153 would recalibrate the risk adjustment models consistent with the methodology finalized for the 2019 benefit year and the incorporation of the blended most recent benefit years of MarketScan® and enrollee-level EDGE data that are available. The proposed regulations address high-cost risk pooling, where we are proposing to implement the same parameters that applied to the 2018 and 2019 benefit years to the 2020 benefit year and beyond. The proposals regarding part 153 also relate to the risk adjustment user fee for the 2020 benefit year and modifications to risk adjustment data validation requirements.

The proposed regulations in 45 CFR part 155 would provide more flexibility related to the training requirements for Navigators by streamlining 20 existing specific training topics into 4 broad categories. We also propose to provide more flexibility to FFE Navigators by making the provision of certain types of assistance, including post-enrollment assistance, permissible for FFE Navigators, not required.¹⁷ We propose

to amend and streamline our regulations related to direct enrollment. We propose to establish a new special enrollment period, at the option of the Exchange, for off-Exchange enrollees who experience a decrease in income and are newly determined to be eligible for APTC by the Exchange. We also propose to increase flexibility for individuals seeking the general hardship exemption by allowing them to alternatively claim the exemption on their federal income tax return for 2018 without obtaining an exemption certificate number from the Exchange. We propose several amendments to the definitions applicable to part 155.

The proposed regulations in 45 CFR part 156 set forth proposals related to cost sharing, including the premium adjustment percentage, the maximum annual limitation on cost sharing, and the reductions in the maximum annual limitation for cost-sharing plan variations for 2020. We propose to use a different premium measure for calculating the premium adjustment percentage for the 2020 benefit year and subsequent benefit years. As we do every year in the HHS notice of benefit and payment parameters, we propose to update the required contribution percentage, the maximum annual limitation on cost sharing, and the reduced maximum annual limitation on cost sharing based on the premium adjustment percentage. We propose to update the FFE and SBE-FP user fee rates for the 2020 benefit year for all issuers participating on the FFEs or SBE-FPs. The proposed regulations in part 156 also include policies to incentivize the use of generic drugs to direct consumers to more cost effective treatment options. In addition, the proposed regulation regarding part 156 includes changes related to direct enrollment.

III. Provisions of the Proposed HHS Notice of Benefit and Payment Parameters for 2020

A. Part 146—Requirements for the Group Health Insurance Market

Section 147.106 implements the guaranteed renewability requirements

understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange; understanding the availability of exemptions from the requirement to maintain MEC and from the individual shared responsibility payment that are claimed through the tax filing process and how to claim them; the Exchange-related components of the premium tax credit reconciliation process; understanding basic concepts and rights related to health coverage and how to use it; and referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice on certain Exchange-related topics.

under the PPACA (applicable to non-grandfathered plans), and §§ 146.152 and 148.122 implement the guaranteed renewability requirements enacted by HIPAA (applicable to both grandfathered and non-grandfathered plans). We propose to make conforming amendments to §§ 146.152 and 148.122, consistent with the proposals in § 147.106 that are discussed below, to ensure consistency in the uniform modification rules to both grandfathered and non-grandfathered coverage. We seek comment on this approach.

B. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

Throughout this rule we propose a number of changes related to policy for prescription drugs that aim to reduce the increases of prescription drug expenditures. Taken together, the proposals and discussions at §§ 146.152, 147.106, 148.122, 156.122, and 156.130 within this proposed rule are meant to offer a suite of changes toward that goal.

Section 147.106(e), implementing guaranteed renewability requirements, enacted by the PPACA, generally prohibits issuers from making modifications to health insurance coverage, other than at the time of yearly coverage renewal. In the 2016 Payment Notice, we expressed concerns about the impact on consumers of mid-year formulary changes. We noted that, under guaranteed renewability requirements and the definitions of “product” and “plan,” issuers generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal. We also stated that certain mid-year changes to drug formularies related to the availability of drugs in the market may be necessary and appropriate.¹⁸

At this time, we believe there are opportunities to increase the use of lower-cost prescription drugs, such as generics, especially as new generic-equivalent drugs become available on the market, by providing additional flexibility for issuers to make mid-year formulary changes, consistent with applicable state law. Therefore, we propose to add § 147.106(e)(5) to allow issuers in the individual, small group, and large group markets, beginning with plan years on or after January 1, 2020, to update their prescription drug formularies by allowing certain mid-year formulary changes, if permitted by applicable state law.

Specifically at § 147.106(e)(5), we propose allowing issuers, for plan years beginning on or after January 1, 2020, to

¹⁷ This assistance includes: Understanding the process of filing Exchange eligibility appeals;

¹⁸ 80 FR at 10822.

make formulary changes during the plan year when a generic equivalent of a prescription drug becomes available on the market, within a reasonable time after that drug becomes available. We propose that the issuer be permitted to modify its plans' formularies to add the generic equivalent drug. At that time, the issuer also would be permitted to remove the equivalent brand drug(s) from the formulary or move the equivalent brand drug(s) to a different cost-sharing tier on the formulary. Any mid-year formulary changes would have to be consistent with the standards applicable to uniform modifications in paragraph (e)(2) or (e)(3).

Issuers, including issuers of grandfathered plans, also would be required to provide enrollees the option to request coverage for a brand drug that was removed from the formulary through the applicable coverage appeal process under § 147.136 or the drug exception request process under § 156.122(c).

Before removing a brand drug from the formulary or moving it to a different cost-sharing tier, a health insurance issuer would be required to notify all plan enrollees of the change in writing a minimum of 60 days prior to initiating the change. This would allow enrollees to begin working with their health care provider on any exception request processes before the change occurs. This notice would identify the name of the brand drug that is the subject of the change, disclose whether the brand drug would be removed from the formulary or placed on a different cost-sharing tier, provide the name of the generic equivalent that will be made available, specify the date the changes will become effective, and state that under the appeals processes outlined in § 147.136 or the exceptions processes outlined in § 156.122(c), enrollees and dependents may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan. We solicit comments on whether a different advance notice period would be more appropriate, such as 90 days or 120 days.

Issuers are not required to use a form notice, but must include certain information in the written notice itself. The specifics of the written notice requirements will be addressed through the PRA process. We recognize that issuers have complex contracting arrangements, that whether a brand drug or its generic equivalent is less costly is a complex question, and that certain states have generic substitution laws.¹⁹

¹⁹ Generic substitution laws may, among other things, address when and how pharmacists or other

We also recognize that some consumers may have concerns about the impact this proposed change may have, given that consumers often purchase a plan based on the plans' prescription drug coverage. However, we believe these concerns may be alleviated given the addition made to the formulary of the generic equivalent, which would generally be more affordable.

We also believe that it is appropriate to permit this flexibility (subject to the uniform modification provision) to make mid-year changes to prescription drug coverage because prescription drugs are a unique benefit category for which this type of mid-year change is warranted. Generic equivalents of brand drugs already approved by the Food and Drug Administration, which contain the same active ingredients as those brand drugs and generally can readily be substituted for the brand drug, are approved for sale throughout the year. New alternatives to covered items and services other than prescription drugs typically do not become available during a given year with the same frequency as in the prescription drug market. While the rationale for this proposed policy related to prescription drugs could arguably be applied to allow similar flexibility for durable medical equipment (DME), we believe that the frequency of changes and potential impact on overall expenditures is greater for prescription drugs and would result in positive cost impacts for both consumers and issuers.²⁰ Nothing under this proposed policy would prevent states or federal agencies that establish standards for federal governmental plans, such as the U.S. Office of Personnel Management (OPM), including with respect to the Federal Employees Health Benefits Program from prohibiting or narrowing the circumstances under which issuers may make such mid-year formulary changes. We encourage issuers of multi-state plans to contact OPM for mid-year formulary change requirements. We also note that this proposal would not require health insurance issuers to avail themselves of this proposal.

We seek comment on all aspects of this proposal, including whether to limit it to individual and small group

health care professionals authorized to dispense medication under state law may substitute a generic drug for a brand drug.

²⁰ In 2017, spending for prescription drugs accounted for 10 percent of health care spending, while DME costs accounted for 2 percent. Centers for Medicare and Medicaid Services. (2018). National Health Expenditures 2017 Highlights. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>.

health insurance issuers. Large group issuers are generally not subject to the limitations on changes that can be made at the time of yearly coverage renewal under the uniform modification provisions, which provides them additional flexibility. If the rule is finalized as proposed, large group health insurance issuers, like issuers in the individual and small group markets, would only be permitted to make mid-year formulary changes that conform to the limitations on modifications under the uniform modification provisions, even though those limitations would continue not to apply to formulary or other changes made at the time of yearly coverage renewal. This would ensure that for any mid-year formulary changes, the product remains the same "product," as defined in § 144.103 (which is based on the uniform modification standards) throughout the entire plan year.

We also propose changes to § 147.106(a) to reflect that paragraph (e) currently provides an exception to the general rule on guaranteed renewability. This is merely a technical correction, not a substantive change. We seek comment on these proposals related to prescription drug benefits and coverage.

Section 147.106 implements the guaranteed renewability requirements under the PPACA (applicable to non-grandfathered plans), and §§ 146.152 and 148.122 implement the guaranteed renewability requirements enacted by HIPAA (applicable to both grandfathered and non-grandfathered plans). We propose to make conforming amendments to §§ 146.152 and 148.122 consistent with the proposals in § 147.106 to ensure consistency in the uniform modification rules to both grandfathered and non-grandfathered coverage.²¹ We seek comment on this approach.

C. Part 148—Requirements for the Individual Health Insurance Market

We propose to make conforming amendments to §§ 146.152 and 148.122, consistent with the proposals in § 147.106 discussed above, to ensure consistency in the uniform modification rules to both grandfathered and non-grandfathered coverage. We seek comment on this approach.

²¹ We note that whether an issuer's removal of a brand drug from its formulary, or its transfer of a brand drug to a different tier under this proposal falls within the parameters of the uniform-modification-of coverage rules is unrelated to and does not determine whether or not the plan maintains its status as a grandfathered plan under 45 CFR 147.140.

D. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Under the Affordable Care Act

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2019,²² both the transitional reinsurance program and permanent risk adjustment program are subject to the fiscal year 2019 sequestration. The federal government's 2019 fiscal year began October 1, 2018. Although the 2016 benefit year was the final year of the transitional reinsurance program, we will continue to make reinsurance payments in the 2019 fiscal year for close-out activities. Therefore, the risk adjustment and reinsurance programs will be sequestered at a rate of 6.2 percent for payments made from fiscal year 2019 resources (that is, funds collected during the 2019 fiscal year).

HHS, in coordination with the OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (Pub. L. 99-177, enacted on December 12, 1985), as amended, and the underlying authority for the reinsurance and risk adjustment programs, the funds that are sequestered in fiscal year 2019 from the reinsurance and risk adjustment programs will become available for payment to issuers in fiscal year 2020 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

2. Provisions and Parameters for the Risk Adjustment Program

In subparts A, B, D, G, and H of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the PPACA that transfers funds from lower-than-average risk, risk adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual and small group markets (including merged markets), inside and outside the Exchanges. In accordance with § 153.310(a), a state that is approved or conditionally approved by the Secretary to operate an Exchange may establish a

risk adjustment program, or have HHS do so on its behalf. HHS did not receive any requests from states to operate risk adjustment for the 2020 benefit year. Therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2020 benefit year.

a. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on that person's age, sex, and diagnoses (also referred to as hierarchical condition categories (HCCs)), producing a risk score. The current structure of these models is described in the 2019 Payment Notice.²³ The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXC) beginning with the 2018 benefit year. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a cost-sharing reduction adjustment that accounts for differences in induced demand at various levels of cost sharing.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score) within a geographic rating area is one of the inputs into the risk adjustment state payment transfer formula, which determines the payment or charge that an issuer will receive or be required to pay for that plan. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

i. Updates to the Risk Adjustment Model Recalibration

We used the 3 most recent years of MarketScan® data available to recalibrate the 2016, 2017, and 2018 benefit year risk adjustment models. For the 2019 benefit year, we recalibrated the models using 2 years of MarketScan® data (2014 and 2015) with 2016 enrollee-level EDGE data. The

2019 benefit year was the first recalibration year in which enrollee-level EDGE data was used for this purpose. This approach used blended, or averaged, coefficients from 3 years of separately solved models to provide stability for the risk adjustment coefficients year-to-year, while reflecting the most recent years' claims experience available.

Similarly, for the 2020 benefit year, we propose to blend the 2 most recent years of enrollee-level EDGE data (2016 and 2017) with the most recent year of MarketScan® data (2017) that will be available. This approach would incorporate the most recent years' claims experience, and would reduce year-to-year changes to risk scores by keeping 1 year's data consistent for the 2019 and 2020 benefit years. It also would continue our efforts to recalibrate the risk adjustment models using actual data from issuers' individual and small group populations and transition from the MarketScan® commercial database that approximates individual and small group market populations. Beginning with the 2021 benefit year's recalibration, we expect to propose solely using enrollee-level EDGE data for model recalibration, and continuing to use the 3 most recent years' data available for the model recalibration to minimize volatility in risk scores, particularly for rare conditions with small sample sizes. We seek comment on our proposal to determine coefficients for the 2020 benefit year based on a blend of separately solved coefficients from the 2016 and 2017 benefit year enrollee-level EDGE data and the 2017 MarketScan® data.

Due to the timing of this proposed rule, we are unable to incorporate the 2017 MarketScan® data in the calculation of the proposed coefficients in this rule. Therefore, the coefficients listed below are based on the 2016 MarketScan® data and 2016 and 2017 benefit year enrollee-level EDGE data. We used the 2016 MarketScan® data for purposes of illustrating draft coefficients in this rule because our experience with MarketScan® data suggests that solved coefficients generally remain stable from year to year. Further, we were able to blend the one older year of MarketScan® data with the 2016 and 2017 enrollee-level EDGE data that would be used as part of the proposed 2020 benefit year recalibration. We therefore believe that the draft coefficients listed below provide a relatively close approximation of what could be anticipated from blending the 2016 and 2017 enrollee-level EDGE data with the 2017 MarketScan® dataset, once the 2017 MarketScan® dataset is available. If we

²² "OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2019", p. 6. February 12, 2018. Available at https://www.whitehouse.gov/wp-content/uploads/2018/02/Sequestration_Report_February_2018.pdf.

²³ See 83 FR 16930 at 16939.

finalize the recalibration proposal outlined herein and are unable to obtain the 2017 MarketScan® data in time for incorporation of coefficients in the final rule, consistent with 45 CFR 153.320(b)(1)(i), and as we have done for certain prior benefit years,²⁴ we would publish the final coefficients for the 2020 benefit year in guidance after the publication of the final rule.

We are not proposing to make changes to the categories included in the HHS risk adjustment models for the 2020 benefit year from those finalized in the 2019 benefit year models. That is, we propose to maintain the same age, sex, enrollment duration, HCC, RXC, and severity categories for the 2020 benefit year models as those used for the 2019 benefit year models.²⁵ However, we are proposing to make a pricing adjustment for one RXC coefficient for the 2020 benefit year adult models. We are cognizant that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score, and therefore, make the risk adjustment transfer results more favorable for the issuer. After reviewing the significant pricing changes in Hepatitis C drugs,²⁶ and consistent with our treatment of other RXCs where we constrain the RXC coefficient to the average cost of the drugs in the category,²⁷ we propose to make a pricing adjustment to the Hepatitis C RXC to mitigate overprescribing incentives in the 2020 benefit year adult models. For the RXC coefficients listed in Table 1 of this proposed rule, we constrained the Hepatitis C coefficient to the average expected costs of Hepatitis C drugs. This has the material effect of reducing the Hepatitis C RXC, and the RXC–HCC interaction coefficients. For the final 2020 benefit year Hepatitis C factors in the adult models, we propose to make an adjustment to the plan liability

associated with Hepatitis C drugs to reflect future market pricing of Hepatitis C drugs before solving for the adult model coefficients; applying an adjustment to the plan liability would ensure that enrollees can continue to receive incremental credit for having both the RXC and HCC for Hepatitis C, and allow for differential plan liability across metal levels.

We seek comment on these proposals. We also seek comment on ways to better anticipate and more precisely adjust the drug categories in the HHS risk adjustment adult models for the rapidly changing drug prices, and the plan liability expenditures calculation in all of the HHS risk adjustment models for the rebates, discounts and price concessions that are passed through to the plans.

We note that for HCCs that have corresponding RXCs and RXC–HCC interaction factors in the proposed 2020 benefit year HHS risk adjustment models, we are observing year-to-year fluctuations in the risk score weights between the HCC, RXC, and RXC–HCC interaction factors. This fluctuation is mainly due to the collinearity between these factors, making the statistical models, and therefore the coefficients solved for these factors, sensitive to small changes in the data. Although the HCC, RXC and RXC–HCC interaction factors may have changed between the 2019 benefit year final models and the factors displayed in this rule, the sum of the factors have remained relatively stable between recalibration updates, except for the deliberate changes we propose above to mitigate overprescribing incentives for certain drugs.

ii. High-Cost Risk Pooling (§ 153.320)

HHS finalized a high-cost risk pool adjustment in the 2018 Payment Notice to account for the incorporation of risk associated with high-cost enrollees in the HHS risk adjustment models. Specifically, we finalized adjusting the models for high-cost enrollees beginning with the 2018 benefit year by excluding a percentage of costs above a certain threshold in the calculation of enrollee-level plan liability risk scores so that risk adjustment factors are calculated without the high-cost risk, since the average risk associated with HCCs and RXCs is better accounted for without the inclusion of the high-cost enrollees. In addition, to account for issuers' risk associated with the high-cost enrollees, issuers receive a percentage of costs above the threshold (coinsurance rate). We set the threshold and coinsurance rate at a level that would continue to incentivize issuers to control costs

while improving the risk prediction of the HHS risk adjustment models. Issuers with high-cost enrollees receive a payment for the percentage of costs above the threshold in their respective transfers. Using claims data submitted to the EDGE servers by issuers of risk adjustment covered plans, we calculate the total amount of paid claims costs for high-cost enrollees based on the threshold and the coinsurance rate. We then calculate a charge as a percentage of the issuers' total premiums in the individual (including catastrophic and non-catastrophic plans and merged market plans) or small group markets, which is applied to the total transfer amount in each market, thus maintaining the balance of payments and charges within the HHS-operated risk adjustment program. We finalized a threshold of \$1 million and a coinsurance rate of 60 percent across all states for the individual (including catastrophic and non-catastrophic plans and merged market plans) and small group markets for the 2018 and 2019 benefit years.²⁸ For the 2020 benefit year and beyond, we propose to maintain the same parameters that apply to the 2018 and 2019 benefit years, unless amended through notice and comment rulemaking for future benefit years. We believe the \$1 million threshold and 60 percent coinsurance rate would result in total high-cost risk pool payments or charges nationally that are very small as a percentage of premiums for issuers, and would prevent states and issuers with very high-cost enrollees from bearing a disproportionate amount of unpredictable risk. Further, as noted previously in this proposed rule, these parameters are set at a level intended to continue to incentivize issuers to control costs while improving the risk prediction of the HHS risk adjustment models. Maintaining the same threshold and coinsurance rate from year to year would also help promote stability and predictability for issuers in rate setting. We seek comment on this proposal.

iii. List of Factors To Be Employed in the Risk Adjustment Models (§ 153.320)

The factors resulting from the equally weighted blended factors from the 2016 MarketScan® data and the 2016 and 2017 enrollee-level EDGE data separately solved models, including the proposed constraints for the Hepatitis C RXC coefficient, are shown in Tables 1, 3, and 4. As detailed above, we used 2016 MarketScan® data for purposes of illustrating coefficients in this proposed rule because our experience with

²⁴ For example, see 2018 Payment Notice final rule, 81 FR 94058 (December 22, 2016).

²⁵ See 83 FR 16939.

²⁶ See <http://www.gilead.com/news/press-releases/2018/9/gilead-subsidiary-to-launch-authorized-generics-of-epclusa-sofosbuvirvelpatasvir-and-harvoni-ledipasvirsofosbuvir-for-the-treatment-of-chronic-hepatitis-c>.

Also see <https://news.abbvie.com/news/abbvie-receives-us-fda-approval-mavyret-glecaprevirpibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm>.

²⁷ See Section 4.0, "Constraints on RXC Coefficients to Limit Incentives for Inappropriate Prescribing" of the Creation of the 2018 Benefit Year HHS-Operated Risk Adjustment Adult Models Draft Prescription Drug (RXCU) to HHS Drug Classes (RXC) Crosswalk Memo. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf>.

²⁸ See 81 FR 94058 at 94080 and 83 FR 16930 at 16943.

MarketScan® data suggests that solved coefficients generally remain stable year to year. We therefore believe that the draft factors listed below provide a relatively close approximation of what could be anticipated from blending the 2016 and 2017 enrollee-level EDGE data with the 2017 MarketScan® dataset, once the 2017 MarketScan® dataset becomes available. The adult, child, and

infant models have been truncated to account for the high-cost enrollee pool payment parameters by removing 60 percent of costs above the \$1 million threshold as proposed in this rule. Table 1 contains factors for each adult model, including the age-sex, HCCs, RXCs, RXC-HCC interactions, and enrollment duration coefficients.

Table 2 contains the HHS HCCs in the severity illness indicator variable. Table 3 contains the factors for each child model. Table 4 contains the factors for each infant model. Tables 5 and 6 contain the HCCs included in the infant model maturity and severity categories, respectively.

TABLE 1—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors						
	Age 21–24, Male	0.156	0.124	0.087	0.051	0.047
	Age 25–29, Male	0.154	0.121	0.083	0.046	0.041
	Age 30–34, Male	0.187	0.147	0.102	0.057	0.051
	Age 35–39, Male	0.221	0.174	0.120	0.066	0.060
	Age 40–44, Male	0.263	0.211	0.150	0.089	0.082
	Age 45–49, Male	0.307	0.247	0.180	0.111	0.103
	Age 50–54, Male	0.391	0.322	0.242	0.161	0.151
	Age 55–59, Male	0.438	0.360	0.273	0.183	0.172
	Age 60–64, Male	0.479	0.392	0.294	0.194	0.181
	Age 21–24, Female	0.237	0.189	0.128	0.068	0.061
	Age 25–29, Female	0.267	0.213	0.145	0.078	0.069
	Age 30–34, Female	0.357	0.290	0.213	0.136	0.127
	Age 35–39, Female	0.428	0.352	0.268	0.186	0.176
	Age 40–44, Female	0.472	0.389	0.296	0.205	0.194
	Age 45–49, Female	0.483	0.395	0.297	0.197	0.185
	Age 50–54, Female	0.525	0.433	0.329	0.221	0.208
	Age 55–59, Female	0.500	0.408	0.302	0.192	0.178
	Age 60–64, Female	0.509	0.412	0.301	0.185	0.170
Diagnosis Factors						
HCC001	HIV/AIDS	4.173	3.838	3.606	3.544	3.538
HCC002	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock ..	7.217	7.014	6.899	6.924	6.931
HCC003	Central Nervous System Infections, Except Viral Meningitis	5.816	5.737	5.683	5.696	5.698
HCC004	Viral or Unspecified Meningitis	4.789	4.58	4.455	4.377	4.369
HCC006	Opportunistic Infections	5.865	5.794	5.748	5.709	5.703
HCC008	Metastatic Cancer	21.512	21.036	20.714	20.742	20.746
HCC009	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	11.444	11.106	10.878	10.843	10.838
HCC010	Non-Hodgkin's Lymphomas and Other Cancers and Tumors	5.259	5.028	4.864	4.787	4.777
HCC011	Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.74	3.515	3.353	3.269	3.258
HCC012	Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.	2.463	2.299	2.175	2.096	2.086
HCC013	Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.	1.093	0.968	0.863	0.747	0.732
HCC018	Pancreas Transplant Status/Complications	3.808	3.608	3.489	3.484	3.485
HCC019	Diabetes with Acute Complications	0.47	0.407	0.347	0.285	0.276
HCC020	Diabetes with Chronic Complications	0.47	0.407	0.347	0.285	0.276
HCC021	Diabetes without Complication	0.47	0.407	0.347	0.285	0.276
HCC023	Protein-Calorie Malnutrition	10.841	10.828	10.818	10.902	10.912
HCC026	Mucopolysaccharidosis	2.438	2.341	2.265	2.206	2.199
HCC027	Lipidoses and Glycogenosis	2.438	2.341	2.265	2.206	2.199
HCC029	Amyloidosis, Porphyria, and Other Metabolic Disorders	2.438	2.341	2.265	2.206	2.199
HCC030	Adrenal, Pituitary, and Other Significant Endocrine Disorders	2.438	2.341	2.265	2.206	2.199
HCC034	Liver Transplant Status/Complications	9.468	9.382	9.324	9.297	9.292
HCC035	End-Stage Liver Disease	4.913	4.709	4.579	4.55	4.546
HCC036	Cirrhosis of Liver	1.267	1.147	1.066	1.003	0.995
HCC037_1	Chronic Viral Hepatitis C	0.8	0.692	0.616	0.552	0.544
HCC037_2	Chronic Hepatitis, Other/Unspecified	0.8	0.692	0.616	0.552	0.544
HCC038	Acute Liver Failure/Disease, Including Neonatal Hepatitis	4.575	4.413	4.31	4.278	4.275
HCC041	Intestine Transplant Status/Complications	27.645	27.629	27.621	27.643	27.65
HCC042	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	8.876	8.644	8.49	8.491	8.492
HCC045	Intestinal Obstruction	5.286	5.051	4.908	4.885	4.884
HCC046	Chronic Pancreatitis	3.808	3.608	3.489	3.484	3.485
HCC047	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.	1.978	1.822	1.716	1.632	1.621
HCC048	Inflammatory Bowel Disease	2.851	2.668	2.531	2.44	2.428
HCC054	Necrotizing Fasciitis	5.225	5.043	4.919	4.918	4.919
HCC055	Bone/Joint/Muscle Infections/Necrosis	5.225	5.043	4.919	4.918	4.919
HCC056	Rheumatoid Arthritis and Specified Autoimmune Disorders	4.286	4.06	3.896	3.848	3.842
HCC057	Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.839	0.726	0.63	0.516	0.5
HCC061	Osteogenesis Imperfecta and Other Osteodystrophies	2.625	2.441	2.308	2.229	2.218
HCC062	Congenital/Developmental Skeletal and Connective Tissue Disorders	2.625	2.441	2.308	2.229	2.218
HCC063	Cleft Lip/Cleft Palate	1.863	1.716	1.608	1.52	1.511
HCC066	Hemophilia	62.079	61.707	61.443	61.446	61.447
HCC067	Myelodysplastic Syndromes and Myelofibrosis	11.971	11.848	11.764	11.754	11.752

TABLE 1—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
HCC068	Aplastic Anemia	11.971	11.848	11.764	11.754	11.752
HCC069	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	6.945	6.842	6.766	6.732	6.728
HCC070	Sickle Cell Anemia (Hb-SS)	6.945	6.842	6.766	6.732	6.728
HCC071	Thalassemia Major	6.945	6.842	6.766	6.732	6.728
HCC073	Combined and Other Severe Immunodeficiencies	4.768	4.642	4.557	4.547	4.545
HCC074	Disorders of the Immune Mechanism	4.768	4.642	4.557	4.547	4.545
HCC075	Coagulation Defects and Other Specified Hematological Disorders	2.804	2.716	2.651	2.614	2.609
HCC081	Drug Psychosis	3.383	3.152	2.985	2.848	2.829
HCC082	Drug Dependence	3.383	3.152	2.985	2.848	2.829
HCC087	Schizophrenia	2.833	2.599	2.438	2.332	2.319
HCC088	Major Depressive and Bipolar Disorders	1.686	1.518	1.389	1.263	1.246
HCC089	Reactive and Unspecified Psychosis, Delusional Disorders	1.633	1.484	1.369	1.247	1.23
HCC090	Personality Disorders	1.171	1.053	0.943	0.814	0.797
HCC094	Anorexia/Bulimia Nervosa	2.484	2.323	2.199	2.115	2.103
HCC096	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	5.256	5.16	5.089	5.029	5.02
HCC097	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.	1.431	1.337	1.26	1.192	1.184
HCC102	Autistic Disorder	1.171	1.053	0.943	0.814	0.797
HCC103	Pervasive Developmental Disorders, Except Autistic Disorder	1.171	1.053	0.943	0.814	0.797
HCC106	Traumatic Complete Lesion Cervical Spinal Cord	10.509	10.376	10.285	10.261	10.258
HCC107	Quadriplegia	10.509	10.376	10.285	10.261	10.258
HCC108	Traumatic Complete Lesion Dorsal Spinal Cord	7.28	7.122	7.013	6.977	6.971
HCC109	Paraplegia	7.28	7.122	7.013	6.977	6.971
HCC110	Spinal Cord Disorders/Injuries	5.144	4.923	4.775	4.733	4.727
HCC111	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	1.157	0.987	0.899	0.821	0.811
HCC112	Quadriplegic Cerebral Palsy	0.544	0.472	0.434	0.412	0.41
HCC113	Cerebral Palsy, Except Quadriplegic	0.014	0	0	0	0
HCC114	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.	0.719	0.598	0.512	0.443	0.434
HCC115	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	5.452	5.328	5.247	5.234	5.232
HCC117	Muscular Dystrophy	1.931	1.791	1.692	1.594	1.579
HCC118	Multiple Sclerosis	3.977	3.768	3.619	3.539	3.528
HCC119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.	1.931	1.791	1.692	1.594	1.579
HCC120	Seizure Disorders and Convulsions	1.272	1.127	1.02	0.922	0.909
HCC121	Hydrocephalus	7.157	7.057	6.982	6.966	6.964
HCC122	Non-Traumatic Coma, and Brain Compression/Anoxic Damage	7.845	7.701	7.598	7.581	7.578
HCC125	Respirator Dependence/Tracheostomy Status	24.729	24.677	24.64	24.727	24.736
HCC126	Respiratory Arrest	7.301	7.135	7.037	7.105	7.117
HCC127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.	7.301	7.135	7.037	7.105	7.117
HCC128	Heart Assistive Device/Artificial Heart	26.627	26.441	26.323	26.356	26.362
HCC129	Heart Transplant	26.627	26.441	26.323	26.356	26.362
HCC130	Congestive Heart Failure	2.564	2.466	2.4	2.387	2.387
HCC131	Acute Myocardial Infarction	6.677	6.408	6.236	6.283	6.292
HCC132	Unstable Angina and Other Acute Ischemic Heart Disease	4.921	4.63	4.463	4.448	4.449
HCC135	Heart Infection/Inflammation, Except Rheumatic	5.682	5.566	5.487	5.459	5.456
HCC142	Specified Heart Arrhythmias	2.439	2.304	2.205	2.133	2.125
HCC145	Intracranial Hemorrhage	7.172	6.911	6.743	6.701	6.697
HCC146	Ischemic or Unspecified Stroke	1.917	1.769	1.684	1.641	1.637
HCC149	Cerebral Aneurysm and Arteriovenous Malformation	2.665	2.491	2.375	2.295	2.285
HCC150	Hemiplegia/Hemiparesis	4.306	4.195	4.129	4.172	4.18
HCC151	Monoplegia, Other Paralytic Syndromes	3.069	2.941	2.854	2.806	2.8
HCC153	Atherosclerosis of the Extremities with Ulceration or Gangrene	8.757	8.663	8.604	8.68	8.691
HCC154	Vascular Disease with Complications	6.185	6.039	5.939	5.915	5.912
HCC156	Pulmonary Embolism and Deep Vein Thrombosis	3.378	3.232	3.131	3.06	3.051
HCC158	Lung Transplant Status/Complications	22.316	22.217	22.149	22.211	22.218
HCC159	Cystic Fibrosis	6.742	6.485	6.296	6.272	6.269
HCC160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.871	0.764	0.671	0.572	0.559
HCC161	Asthma	0.871	0.764	0.671	0.572	0.559
HCC162	Fibrosis of Lung and Other Lung Disorders	1.939	1.836	1.768	1.717	1.709
HCC163	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	6.337	6.305	6.282	6.282	6.281
HCC183	Kidney Transplant Status	6.199	6.014	5.894	5.835	5.84
HCC184	End Stage Renal Disease	25.151	24.907	24.748	24.906	25
HCC187	Chronic Kidney Disease, Stage 5	0.89	0.843	0.815	0.826	0.834
HCC188	Chronic Kidney Disease, Stage 4	0.89	0.843	0.815	0.826	0.834
HCC203	Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism.	1.003	0.871	0.747	0.556	0.528
HCC204	Miscarriage with Complications	1.003	0.871	0.747	0.556	0.528
HCC205	Miscarriage with No or Minor Complications	1.003	0.871	0.747	0.556	0.528
HCC207	Completed Pregnancy With Major Complications	3.267	2.869	2.658	2.336	2.295
HCC208	Completed Pregnancy With Complications	3.267	2.869	2.658	2.336	2.295
HCC209	Completed Pregnancy with No or Minor Complications	3.267	2.869	2.658	2.336	2.295
HCC217	Chronic Ulcer of Skin, Except Pressure	1.925	1.819	1.75	1.725	1.722
HCC226	Hip Fractures and Pathological Vertebral or Humerus Fractures	8.32	8.091	7.941	7.959	7.961
HCC227	Pathological Fractures, Except of Vertebrae, Hip, or Humerus	6.002	5.848	5.746	5.709	5.704
HCC251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	25.922	25.916	25.908	25.939	25.943
HCC253	Artificial Openings for Feeding or Elimination	7.612	7.528	7.472	7.499	7.503
HCC254	Amputation Status, Lower Limb/Amputation Complications	2.739	2.619	2.547	2.555	2.558

TABLE 1—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Interaction Factors						
SEVERE x HCC006	Severe illness x Opportunistic Infections	6.689	6.895	7.031	7.192	7.212
SEVERE x HCC008	Severe illness x Metastatic Cancer	6.689	6.895	7.031	7.192	7.212
SEVERE x HCC009	Severe illness x Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.	6.689	6.895	7.031	7.192	7.212
SEVERE x HCC010	Severe illness x Non-Hodgkin's Lymphomas and Other Cancers and Tumors.	6.689	6.895	7.031	7.192	7.212
SEVERE x HCC115	Severe illness x Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.	6.689	6.895	7.031	7.192	7.212
SEVERE x HCC135	Severe illness x Heart Infection/Inflammation, Except Rheumatic	6.689	6.895	7.031	7.192	7.212
SEVERE x HCC145	Severe illness x Intracranial Hemorrhage	6.689	6.895	7.031	7.192	7.212
SEVERE x G06	Severe illness x HCC group G06 (G06 is HCC Group 6 which includes the following HCCs in the blood disease category: 67, 68).	6.689	6.895	7.031	7.192	7.212
SEVERE x G08	Severe illness x HCC group G08 (G08 is HCC Group 8 which includes the following HCCs in the blood disease category: 73, 74).	6.689	6.895	7.031	7.192	7.212
SEVERE x HCC035	Severe illness x End-Stage Liver Disease	0.752	0.815	0.857	0.997	1.014
SEVERE x HCC038	Severe illness x Acute Liver Failure/Disease, Including Neonatal Hepatitis	0.752	0.815	0.857	0.997	1.014
SEVERE x HCC153	Severe illness x Atherosclerosis of the Extremities with Ulceration or Gangrene.	0.752	0.815	0.857	0.997	1.014
SEVERE x HCC154	Severe illness x Vascular Disease with Complications	0.752	0.815	0.857	0.997	1.014
SEVERE x HCC163	Severe illness x Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.	0.752	0.815	0.857	0.997	1.014
SEVERE x HCC253	Severe illness x Artificial Openings for Feeding or Elimination	0.752	0.815	0.857	0.997	1.014
SEVERE x G03	Severe illness x HCC group G03 (G03 is HCC Group 3 which includes the following HCCs in the musculoskeletal disease category: 54, 55).	0.752	0.815	0.857	0.997	1.014
Enrollment Duration Factors						
	1 month of enrollment	0.320	0.282	0.254	0.239	0.237
	2 months of enrollment	0.284	0.247	0.221	0.207	0.206
	3 months of enrollment	0.270	0.235	0.208	0.194	0.192
	4 months of enrollment	0.235	0.204	0.177	0.164	0.163
	5 months of enrollment	0.206	0.178	0.152	0.138	0.137
	6 months of enrollment	0.182	0.158	0.136	0.123	0.121
	7 months of enrollment	0.139	0.120	0.101	0.090	0.089
	8 months of enrollment	0.100	0.086	0.072	0.063	0.062
	9 months of enrollment	0.059	0.051	0.042	0.037	0.036
	10 months of enrollment	0.024	0.021	0.019	0.017	0.016
	11 months of enrollment	0.024	0.021	0.019	0.017	0.016
Prescription Drug Factors						
RXC 01	Anti-HIV Agents	7.550	6.937	6.500	6.183	6.145
RXC 02	Anti-Hepatitis C (HCV) Agents	8.134	8.134	8.134	8.134	8.134
RXC 03	Antiarrhythmics	0.128	0.117	0.109	0.074	0.057
RXC 04	Phosphate Binders	1.989	1.977	1.956	1.911	1.766
RXC 05	Inflammatory Bowel Disease Agents	1.699	1.542	1.421	1.246	1.221
RXC 06	Insulin	1.754	1.586	1.411	1.217	1.191
RXC 07	Anti-Diabetic Agents, Except Insulin and Metformin Only	0.696	0.595	0.500	0.362	0.342
RXC 08	Multiple Sclerosis Agents	20.745	19.805	19.185	19.063	19.046
RXC 09	Immune Suppressants and Immunomodulators	13.889	13.300	12.918	13.002	13.015
RXC 10	Cystic Fibrosis Agents	12.787	12.411	12.191	12.224	12.231
RXC 01 x HCC001	Additional effect for enrollees with RXC 01 (Anti-HIV Agents) and HCC 001 (HIV/AIDS).	-0.897	-0.571	-0.320	0.104	0.155
RXC 02 x HCC037_1, 036, 035, 034.	Additional effect for enrollees with RXC 02 (Anti-Hepatitis C (HCV) Agents) and (HCC 037_1 (Chronic Viral Hepatitis C) or 036 (Cirrhosis of Liver) or 035 (End-Stage Liver Disease) or 034 (Liver Transplant Status/Complications)).	0.263	0.484	0.641	0.712	0.720
RXC 03 x HCC142	Additional effect for enrollees with RxC 03 (Antiarrhythmics) and HCC 142 (Specified Heart Arrhythmias).	0.000	0.000	0.000	0.000	0.000
RXC 04 x HCC184, 183, 187, 188.	Additional effect for enrollees with RxC 04 (Phosphate Binders) and (HCC 184 (End Stage Renal Disease) or 183 (Kidney Transplant Status) or 187 (Chronic Kidney Disease, Stage 5) or 188 (Chronic Kidney Disease, Severe Stage 4)).	0.000	0.000	0.000	0.000	0.000
RXC 05 x HCC048, 041	Additional effect for enrollees with RxC 05 (Inflammatory Bowel Disease Agents) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	-0.889	-0.828	-0.759	-0.700	-0.692
RXC 06 x HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 06 (Insulin) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	0.373	0.332	0.391	0.440	0.445
RXC 07 x HCC018, 019, 020, 021.	Additional effect for enrollees with RxC 07 (Anti-Diabetic Agents, Except Insulin and Metformin Only) and (HCC 018 (Pancreas Transplant Status/Complications) or 019 (Diabetes with Acute Complications) or 020 (Diabetes with Chronic Complications) or 021 (Diabetes without Complication)).	-0.322	-0.278	-0.229	-0.187	-0.182
RXC 08 x HCC118	Additional effect for enrollees with RxC 08 (Multiple Sclerosis Agents) and HCC 118 (Multiple Sclerosis).	-1.470	-0.952	-0.608	-0.303	-0.259

TABLE 1—PROPOSED ADULT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

HCC or RXC No.	Factor	Platinum	Gold	Silver	Bronze	Catastrophic
RXC 09 x HCC056 or 057 and 048 or 041.	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)) and (HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders) or 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders)).	0.620	0.735	0.828	0.916	0.928
RXC 09 x HCC056	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 056 (Rheumatoid Arthritis and Specified Autoimmune Disorders).	-4.286	-4.060	-3.896	-3.848	-3.842
RXC 09 x HCC057	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and HCC 057 (Systemic Lupus Erythematosus and Other Autoimmune Disorders).	-0.839	-0.726	-0.630	-0.516	-0.500
RXC 09 x HCC048, 041	Additional effect for enrollees with RxC 09 (Immune Suppressants and Immunomodulators) and (HCC 048 (Inflammatory Bowel Disease) or 041 (Intestine Transplant Status/Complications)).	-1.853	-1.676	-1.573	-1.500	-1.491
RXC 10 x HCC159, 158	Additional effect for enrollees with RxC 10 (Cystic Fibrosis Agents) and (HCC 159 (Cystic Fibrosis) or 158 (Lung Transplant Status/Complications)).	48.353	48.538	48.622	48.768	48.783

TABLE 2—HHS HCCs IN THE SEVERITY ILLNESS INDICATOR VARIABLE

HCC/description
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Peritonitis/Gastrointestinal Perforation/Necrotizing Enter colitis.
Seizure Disorders and Convulsions.
Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Respirator Dependence/Tracheostomy Status.
Respiratory Arrest.
Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Pulmonary Embolism and Deep Vein Thrombosis.

TABLE 3—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Demographic Factors					
Age 2–4, Male	0.202	0.159	0.111	0.067	0.062
Age 5–9, Male	0.142	0.107	0.067	0.035	0.031
Age 10–14, Male	0.182	0.147	0.103	0.068	0.065
Age 15–20, Male	0.239	0.195	0.142	0.096	0.091
Age 2–4, Female	0.153	0.118	0.080	0.048	0.044
Age 5–9, Female	0.094	0.065	0.033	0.009	0.007
Age 10–14, Female	0.172	0.137	0.097	0.066	0.063
Age 15–20, Female	0.259	0.205	0.140	0.080	0.073
Diagnosis Factors					
HIV/AIDS	4.611	4.183	3.893	3.780	3.768
Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock	12.287	12.089	11.976	11.970	11.972
Central Nervous System Infections, Except Viral Meningitis	7.545	7.385	7.283	7.288	7.289
Viral or Unspecified Meningitis	2.963	2.733	2.588	2.429	2.408
Opportunistic Infections	13.893	13.845	13.807	13.777	13.772
Metastatic Cancer	33.270	33.040	32.867	32.878	32.878
Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia	8.930	8.681	8.496	8.406	8.394
Non-Hodgkin's Lymphomas and Other Cancers and Tumors	7.078	6.840	6.663	6.554	6.539
Colorectal, Breast (Age < 50), Kidney, and Other Cancers	3.504	3.333	3.200	3.084	3.067
Breast (Age 50+) and Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors	3.504	3.333	3.200	3.084	3.067
Thyroid Cancer, Melanoma, Neurofibromatosis, and Other Cancers and Tumors	0.980	0.860	0.756	0.641	0.625
Pancreas Transplant Status/Complications	25.040	24.763	24.576	24.596	24.599
Diabetes with Acute Complications	2.657	2.318	2.114	1.837	1.803
Diabetes with Chronic Complications	2.657	2.318	2.114	1.837	1.803
Diabetes without Complication	2.657	2.318	2.114	1.837	1.803
Protein-Calorie Malnutrition	14.512	14.408	14.335	14.372	14.376
Mucopolysaccharidosis	6.393	6.178	6.015	5.966	5.960
Lipidoses and Glycogenosis	6.393	6.178	6.015	5.966	5.960
Congenital Metabolic Disorders, Not Elsewhere Classified	6.393	6.178	6.015	5.966	5.960

TABLE 3—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Amyloidosis, Porphyria, and Other Metabolic Disorders	6.393	6.178	6.015	5.966	5.960
Adrenal, Pituitary, and Other Significant Endocrine Disorders	6.393	6.178	6.015	5.966	5.960
Liver Transplant Status/Complications	25.040	24.763	24.576	24.596	24.599
End-Stage Liver Disease	16.435	16.242	16.115	16.121	16.122
Cirrhosis of Liver	5.140	5.020	4.929	4.917	4.916
Chronic Viral Hepatitis C	5.140	5.020	4.929	4.917	4.916
Chronic Hepatitis, Other/Unspecified	0.351	0.272	0.207	0.174	0.171
Acute Liver Failure/Disease, Including Neonatal Hepatitis	10.604	10.503	10.440	10.464	10.467
Intestine Transplant Status/Complications	25.040	24.763	24.576	24.596	24.599
Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis	11.608	11.319	11.124	11.105	11.105
Intestinal Obstruction	4.466	4.269	4.121	4.015	4.002
Chronic Pancreatitis	11.424	11.182	11.022	11.002	10.998
Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption	2.537	2.423	2.328	2.237	2.224
Inflammatory Bowel Disease	8.035	7.623	7.338	7.231	7.216
Necrotizing Fasciitis	3.791	3.578	3.421	3.339	3.329
Bone/Joint/Muscle Infections/Necrosis	3.791	3.578	3.421	3.339	3.329
Rheumatoid Arthritis and Specified Autoimmune Disorders	4.536	4.289	4.098	4.012	4.003
Systemic Lupus Erythematosus and Other Autoimmune Disorders	0.625	0.508	0.403	0.297	0.287
Osteogenesis Imperfecta and Other Osteodystrophies	1.254	1.144	1.050	0.970	0.959
Congenital/Developmental Skeletal and Connective Tissue Disorders	1.254	1.144	1.050	0.970	0.959
Cleft Lip/Cleft Palate	1.308	1.132	1.003	0.875	0.859
Hemophilia	63.950	63.414	63.032	62.993	62.988
Myelodysplastic Syndromes and Myelofibrosis	15.020	14.898	14.815	14.791	14.788
Aplastic Anemia	15.020	14.898	14.815	14.791	14.788
Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	6.294	6.099	5.957	5.876	5.866
Sickle Cell Anemia (Hb-SS)	6.294	6.099	5.957	5.876	5.866
Thalassemia Major	6.294	6.099	5.957	5.876	5.866
Combined and Other Severe Immunodeficiencies	5.190	5.046	4.940	4.889	4.881
Disorders of the Immune Mechanism	5.190	5.046	4.940	4.889	4.881
Coagulation Defects and Other Specified Hematological Disorders	4.235	4.117	4.023	3.948	3.938
Drug Psychosis	5.458	5.181	5.004	4.916	4.907
Drug Dependence	5.458	5.181	5.004	4.916	4.907
Schizophrenia	4.740	4.391	4.152	4.003	3.982
Major Depressive and Bipolar Disorders	2.636	2.401	2.219	2.044	2.021
Reactive and Unspecified Psychosis, Delusional Disorders	2.409	2.199	2.026	1.860	1.838
Personality Disorders	0.495	0.398	0.294	0.162	0.144
Anorexia/Bulimia Nervosa	2.145	1.951	1.799	1.696	1.682
Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes	1.587	1.444	1.343	1.261	1.250
Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes	1.587	1.444	1.343	1.261	1.250
Autistic Disorder	2.409	2.199	2.026	1.860	1.838
Pervasive Developmental Disorders, Except Autistic Disorder	0.517	0.433	0.337	0.221	0.206
Traumatic Complete Lesion Cervical Spinal Cord	8.958	8.915	8.889	8.959	8.970
Quadriplegia	8.958	8.915	8.889	8.959	8.970
Traumatic Complete Lesion Dorsal Spinal Cord	6.394	6.185	6.048	6.010	6.003
Paraplegia	6.394	6.185	6.048	6.010	6.003
Spinal Cord Disorders/Injuries	3.906	3.725	3.590	3.500	3.486
Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease	14.768	14.524	14.336	14.254	14.245
Quadriplegic Cerebral Palsy	2.129	1.935	1.833	1.835	1.837
Cerebral Palsy, Except Quadriplegic	0.075	0.023	0.000	0.000	0.000
Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies	1.530	1.401	1.310	1.242	1.234
Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy	10.932	10.765	10.651	10.665	10.666
Muscular Dystrophy	2.931	2.750	2.624	2.513	2.500
Multiple Sclerosis	10.587	10.201	9.935	9.905	9.901
Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	2.931	2.750	2.624	2.513	2.500
Seizure Disorders and Convulsions	2.059	1.902	1.765	1.624	1.605
Hydrocephalus	4.187	4.075	3.994	3.966	3.963
Non-Traumatic Coma, and Brain Compression/Anoxic Damage	5.415	5.281	5.178	5.128	5.122

TABLE 3—PROPOSED CHILD RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

Factor	Platinum	Gold	Silver	Bronze	Catastrophic
Respirator Dependence/Tracheostomy Status	31.093	30.989	30.935	31.080	31.098
Respiratory Arrest	9.405	9.149	8.993	8.948	8.944
Cardio-Respiratory Failure and Shock, Including Res- piratory Distress Syndromes	9.405	9.149	8.993	8.948	8.944
Heart Assistive Device/Artificial Heart	25.040	24.763	24.576	24.596	24.599
Heart Transplant	25.040	24.763	24.576	24.596	24.599
Congestive Heart Failure	6.029	5.921	5.840	5.798	5.791
Acute Myocardial Infarction	7.344	7.228	7.177	7.172	7.172
Unstable Angina and Other Acute Ischemic Heart Disease	3.504	3.402	3.332	3.315	3.316
Heart Infection/Inflammation, Except Rheumatic	11.511	11.410	11.340	11.333	11.332
Hypoplastic Left Heart Syndrome and Other Severe Con- genital Heart Disorders	3.677	3.535	3.395	3.291	3.277
Major Congenital Heart/Circulatory Disorders	1.134	1.035	0.919	0.811	0.798
Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Dis- orders	0.881	0.792	0.696	0.609	0.598
Specified Heart Arrhythmias	3.476	3.315	3.184	3.105	3.094
Intracranial Hemorrhage	12.102	11.890	11.755	11.749	11.750
Ischemic or Unspecified Stroke	3.871	3.785	3.733	3.727	3.729
Cerebral Aneurysm and Arteriovenous Malformation	3.267	3.093	2.973	2.888	2.878
Hemiplegia/Hemiparesis	4.268	4.144	4.058	3.991	3.981
Monoplegia, Other Paralytic Syndromes	3.081	2.919	2.807	2.735	2.723
Atherosclerosis of the Extremities with Ulceration or Gan- grene	12.857	12.610	12.435	12.371	12.360
Vascular Disease with Complications	9.797	9.675	9.591	9.613	9.616
Pulmonary Embolism and Deep Vein Thrombosis	15.445	15.336	15.272	15.286	15.289
Lung Transplant Status/Complications	25.040	24.763	24.576	24.596	24.599
Cystic Fibrosis	25.040	24.763	24.576	24.596	24.599
Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	0.374	0.308	0.224	0.138	0.128
Asthma	0.374	0.308	0.224	0.138	0.128
Fibrosis of Lung and Other Lung Disorders	2.370	2.276	2.185	2.110	2.100
Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections	6.769	6.708	6.661	6.681	6.683
Kidney Transplant Status	10.730	10.468	10.302	10.253	10.248
End Stage Renal Disease	30.597	30.449	30.350	30.434	30.447
Chronic Kidney Disease, Stage 5	4.660	4.547	4.456	4.378	4.368
Chronic Kidney Disease, Severe (Stage 4)	4.660	4.547	4.456	4.378	4.368
Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	0.871	0.728	0.586	0.372	0.341
Miscarriage with Complications	0.871	0.728	0.586	0.372	0.341
Miscarriage with No or Minor Complications	0.871	0.728	0.586	0.372	0.341
Completed Pregnancy With Major Complications	2.793	2.422	2.207	1.846	1.794
Completed Pregnancy With Complications	2.793	2.422	2.207	1.846	1.794
Completed Pregnancy with No or Minor Complications	2.793	2.422	2.207	1.846	1.794
Chronic Ulcer of Skin, Except Pressure	2.682	2.590	2.504	2.434	2.427
Hip Fractures and Pathological Vertebral or Humerus Fractures	6.615	6.304	6.079	5.971	5.961
Pathological Fractures, Except of Vertebrae, Hip, or Hu- merus	2.459	2.300	2.161	2.013	1.994
Stem Cell, Including Bone Marrow, Transplant Status/ Complications	25.040	24.763	24.576	24.596	24.599
Artificial Openings for Feeding or Elimination	10.982	10.855	10.790	10.886	10.900
Amputation Status, Lower Limb/Amputation Complications	5.801	5.550	5.379	5.260	5.242

TABLE 4—PROPOSED INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Extremely Immature * Severity Level 5 (Highest)	235.032	233.488	232.362	232.346	232.348
Extremely Immature * Severity Level 4	151.475	149.762	148.512	148.339	148.323
Extremely Immature * Severity Level 3	32.324	31.070	30.143	29.908	29.888
Extremely Immature * Severity Level 2	32.324	31.070	30.143	29.908	29.888
Extremely Immature * Severity Level 1 (Lowest)	32.324	31.070	30.143	29.908	29.888
Immature *Severity Level 5 (Highest)	147.235	145.696	144.571	144.525	144.518
Immature *Severity Level 4	71.633	70.103	68.980	68.867	68.853
Immature *Severity Level 3	32.324	31.070	30.143	29.908	29.888
Immature *Severity Level 2	24.191	22.948	22.048	21.783	21.752
Immature *Severity Level 1 (Lowest)	23.385	22.183	21.291	20.988	20.950
Premature/Multiples * Severity Level 5 (Highest)	103.160	101.773	100.762	100.642	100.628
Premature/Multiples * Severity Level 4	26.232	24.897	23.942	23.684	23.658

TABLE 4—PROPOSED INFANT RISK ADJUSTMENT MODEL FACTORS FOR 2020 BENEFIT YEAR—Continued

Group	Platinum	Gold	Silver	Bronze	Catastrophic
Premature/Multiples * Severity Level 3	13.556	12.549	11.807	11.337	11.281
Premature/Multiples * Severity Level 2	8.366	7.612	6.984	6.350	6.260
Premature/Multiples * Severity Level 1 (Lowest)	5.323	4.803	4.276	3.736	3.670
Term *Severity Level 5 (Highest)	78.324	77.140	76.266	76.059	76.035
Term *Severity Level 4	13.891	13.024	12.388	11.954	11.904
Term *Severity Level 3	5.671	5.137	4.631	4.060	3.982
Term *Severity Level 2	3.599	3.195	2.719	2.122	2.049
Term *Severity Level 1 (Lowest)	1.619	1.412	1.037	0.702	0.672
Age1 *Severity Level 5 (Highest)	56.287	55.575	55.039	54.927	54.915
Age1 *Severity Level 4	10.505	9.976	9.550	9.263	9.230
Age1 *Severity Level 3	3.079	2.821	2.586	2.384	2.360
Age1 *Severity Level 2	1.932	1.734	1.531	1.322	1.296
Age1 *Severity Level 1 (Lowest)	0.527	0.480	0.424	0.376	0.370
Age 0 Male	0.623	0.574	0.537	0.467	0.456
Age 1 Male	0.120	0.106	0.092	0.073	0.070

TABLE 5—HHS HCCs INCLUDED IN INFANT MODEL MATURITY CATEGORIES

Maturity category	HCC/description
Extremely Immature	Extremely Immature Newborns, Birth weight < 500 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 500–749 Grams.
Extremely Immature	Extremely Immature Newborns, Including Birth weight 750–999 Grams.
Immature	Premature Newborns, Including Birth weight 1000–1499 Grams.
Immature	Premature Newborns, Including Birth weight 1500–1999 Grams.
Premature/Multiples	Premature Newborns, Including Birth weight 2000–2499 Grams.
Premature/Multiples	Other Premature, Low Birth weight, Malnourished, or Multiple Birth Newborns.
Term	Term or Post-Term Singleton Newborn, Normal or High Birth weight.
Age 1	All age 1 infants.

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES

Severity category	HCC/description
Severity Level 5 (Highest)	Metastatic Cancer.
Severity Level 5	Pancreas Transplant Status/Complications.
Severity Level 5	Liver Transplant Status/Complications.
Severity Level 5	End-Stage Liver Disease.
Severity Level 5	Intestine Transplant Status/Complications.
Severity Level 5	Peritonitis/Gastrointestinal Perforation/Necrotizing Enterocolitis.
Severity Level 5	Respirator Dependence/Tracheostomy Status.
Severity Level 5	Heart Assistive Device/Artificial Heart.
Severity Level 5	Heart Transplant.
Severity Level 5	Congestive Heart Failure.
Severity Level 5	Hypoplastic Left Heart Syndrome and Other Severe Congenital Heart Disorders.
Severity Level 5	Lung Transplant Status/Complications.
Severity Level 5	Kidney Transplant Status.
Severity Level 5	End Stage Renal Disease.
Severity Level 5	Stem Cell, Including Bone Marrow, Transplant Status/Complications.
Severity Level 4	Septicemia, Sepsis, Systemic Inflammatory Response Syndrome/Shock.
Severity Level 4	Lung, Brain, and Other Severe Cancers, Including Pediatric Acute Lymphoid Leukemia.
Severity Level 4	Mucopolysaccharidosis.
Severity Level 4	Major Congenital Anomalies of Diaphragm, Abdominal Wall, and Esophagus, Age < 2.
Severity Level 4	Myelodysplastic Syndromes and Myelofibrosis.
Severity Level 4	Aplastic Anemia.
Severity Level 4	Combined and Other Severe Immunodeficiencies.
Severity Level 4	Traumatic Complete Lesion Cervical Spinal Cord.
Severity Level 4	Quadriplegia.
Severity Level 4	Amyotrophic Lateral Sclerosis and Other Anterior Horn Cell Disease.
Severity Level 4	Quadriplegic Cerebral Palsy.
Severity Level 4	Myasthenia Gravis/Myoneural Disorders and Guillain-Barre Syndrome/Inflammatory and Toxic Neuropathy.
Severity Level 4	Non-Traumatic Coma, Brain Compression/Anoxic Damage.
Severity Level 4	Respiratory Arrest.
Severity Level 4	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.
Severity Level 4	Acute Myocardial Infarction.
Severity Level 4	Heart Infection/Inflammation, Except Rheumatic.
Severity Level 4	Major Congenital Heart/Circulatory Disorders.
Severity Level 4	Intracranial Hemorrhage.
Severity Level 4	Ischemic or Unspecified Stroke.

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC/description
Severity Level 4	Vascular Disease with Complications.
Severity Level 4	Pulmonary Embolism and Deep Vein Thrombosis.
Severity Level 4	Aspiration and Specified Bacterial Pneumonias and Other Severe Lung Infections.
Severity Level 4	Chronic Kidney Disease, Stage 5.
Severity Level 4	Hip Fractures and Pathological Vertebral or Humerus Fractures.
Severity Level 4	Artificial Openings for Feeding or Elimination.
Severity Level 3	HIV/AIDS.
Severity Level 3	Central Nervous System Infections, Except Viral Meningitis.
Severity Level 3	Opportunistic Infections.
Severity Level 3	Non-Hodgkin's Lymphomas and Other Cancers and Tumors.
Severity Level 3	Colorectal, Breast (Age < 50), Kidney and Other Cancers.
Severity Level 3	Breast (Age 50+), Prostate Cancer, Benign/Uncertain Brain Tumors, and Other Cancers and Tumors.
Severity Level 3	Lipidoses and Glycogenosis.
Severity Level 3	Adrenal, Pituitary, and Other Significant Endocrine Disorders.
Severity Level 3	Acute Liver Failure/Disease, Including Neonatal Hepatitis.
Severity Level 3	Intestinal Obstruction.
Severity Level 3	Necrotizing Fasciitis.
Severity Level 3	Bone/Joint/Muscle Infections/Necrosis.
Severity Level 3	Osteogenesis Imperfecta and Other Osteodystrophies.
Severity Level 3	Cleft Lip/Cleft Palate.
Severity Level 3	Hemophilia.
Severity Level 3	Disorders of the Immune Mechanism.
Severity Level 3	Coagulation Defects and Other Specified Hematological Disorders.
Severity Level 3	Prader-Willi, Patau, Edwards, and Autosomal Deletion Syndromes.
Severity Level 3	Traumatic Complete Lesion Dorsal Spinal Cord.
Severity Level 3	Paraplegia.
Severity Level 3	Spinal Cord Disorders/Injuries.
Severity Level 3	Cerebral Palsy, Except Quadriplegic.
Severity Level 3	Muscular Dystrophy.
Severity Level 3	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders.
Severity Level 3	Hydrocephalus.
Severity Level 3	Unstable Angina and Other Acute Ischemic Heart Disease.
Severity Level 3	Atrial and Ventricular Septal Defects, Patent Ductus Arteriosus, and Other Congenital Heart/Circulatory Disorders.
Severity Level 3	Specified Heart Arrhythmias.
Severity Level 3	Cerebral Aneurysm and Arteriovenous Malformation.
Severity Level 3	Hemiplegia/Hemiparesis.
Severity Level 3	Cystic Fibrosis.
Severity Level 3	Fibrosis of Lung and Other Lung Disorders.
Severity Level 3	Pathological Fractures, Except of Vertebrae, Hip, or Humerus.
Severity Level 2	Viral or Unspecified Meningitis.
Severity Level 2	Thyroid, Melanoma, Neurofibromatosis, and Other Cancers and Tumors.
Severity Level 2	Diabetes with Acute Complications.
Severity Level 2	Diabetes with Chronic Complications.
Severity Level 2	Diabetes without Complication.
Severity Level 2	Protein-Calorie Malnutrition.
Severity Level 2	Congenital Metabolic Disorders, Not Elsewhere Classified.
Severity Level 2	Amyloidosis, Porphyria, and Other Metabolic Disorders.
Severity Level 2	Cirrhosis of Liver.
Severity Level 2	Chronic Pancreatitis.
Severity Level 2	Inflammatory Bowel Disease.
Severity Level 2	Rheumatoid Arthritis and Specified Autoimmune Disorders.
Severity Level 2	Systemic Lupus Erythematosus and Other Autoimmune Disorders.
Severity Level 2	Congenital/Developmental Skeletal and Connective Tissue Disorders.
Severity Level 2	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn.
Severity Level 2	Sickle Cell Anemia (Hb-SS).
Severity Level 2	Drug Psychosis.
Severity Level 2	Drug Dependence.
Severity Level 2	Down Syndrome, Fragile X, Other Chromosomal Anomalies, and Congenital Malformation Syndromes.
Severity Level 2	Spina Bifida and Other Brain/Spinal/Nervous System Congenital Anomalies.
Severity Level 2	Seizure Disorders and Convulsions.
Severity Level 2	Monoplegia, Other Paralytic Syndromes.
Severity Level 2	Atherosclerosis of the Extremities with Ulceration or Gangrene.
Severity Level 2	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis.
Severity Level 2	Chronic Ulcer of Skin, Except Pressure.
Severity Level 1 (Lowest)	Chronic Hepatitis.
Severity Level 1	Acute Pancreatitis/Other Pancreatic Disorders and Intestinal Malabsorption.
Severity Level 1	Thalassemia Major.
Severity Level 1	Autistic Disorder.

TABLE 6—HHS HCCs INCLUDED IN INFANT MODEL SEVERITY CATEGORIES—Continued

Severity category	HCC/description
Severity Level 1	Pervasive Developmental Disorders, Except Autistic Disorder.
Severity Level 1	Multiple Sclerosis.
Severity Level 1	Asthma.
Severity Level 1	Chronic Kidney Disease, Severe (Stage 4).
Severity Level 1	Amputation Status, Lower Limb/Amputation Complications.
Severity Level 1	No Severity HCCs.

iv. Cost-Sharing Reduction Adjustments

We propose to continue including an adjustment for the receipt of cost-sharing reductions in the risk adjustment models to account for increased plan liability due to increased utilization of health care services by enrollees receiving cost-sharing reductions in all 50 states and the

District of Columbia. For the 2020 benefit year, to maintain stability and certainty for issuers, we are proposing to maintain the cost-sharing reduction factors finalized in the 2019 Payment Notice.²⁹ See Table 7. We seek comment on this proposal.

Consistent with the approach finalized in the 2017 Payment Notice,³⁰

we will continue to use cost-sharing reduction adjustment factors of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation, as all of Massachusetts' cost-sharing plan variations have actuarial values above 94 percent.

TABLE 7—COST-SHARING REDUCTION ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variant Recipients		
100–150% of FPL	Plan Variation 94%	1.12
150–200% of FPL	Plan Variation 87%	1.12
200–250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12
<300% of FPL	Bronze (60%)	1.15
Limited Cost Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

v. Model Performance Statistics

To evaluate risk adjustment model performance, we examined each model's R-squared statistic and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratios measure the predictive accuracy of a model for different validation groups or subpopulations. The predictive ratio for each of the HHS risk adjustment models is the ratio of the weighted mean

predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation. A subpopulation that is predicted perfectly would have a predictive ratio of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the predictive ratios are in the range of published estimates for concurrent risk adjustment models.³¹ Because we blended the coefficients from separately solved

models based on 2016 MarketScan® data and 2016 and 2017 enrollee-level EDGE data in this proposed rule, we are publishing the R-squared statistic for each model separately to verify their statistical validity. The R-squared statistic for each model is shown in Table 8. We intend to publish updated R-squared statistics to reflect results from the blending of the 2017 MarketScan® and 2016 and 2017 benefit year enrollee-level EDGE datasets used to recalibrate the models for the 2020 benefit year if the proposal is finalized in the final rule.

²⁹ See 83 FR 16930 at 16953.

³⁰ See 81 FR 12203 at 12228.

³¹ Winkleman, Ross and Syed Mehmud. "A Comparative Analysis of Claims-Based Tools for

Health Risk Assessment." Society of Actuaries. April 2007.

TABLE 8—R-SQUARED STATISTIC FOR PROPOSED HHS RISK ADJUSTMENT MODELS

Models	R-squared statistic		
	2016 Enrollee level EDGE data	2017 Enrollee-level EDGE data R-squared	2016 MarketScan® data R-squared
Platinum Adult	0.4336	0.4192	0.4139
Gold Adult	0.4283	0.4127	0.4090
Silver Adult	0.4241	0.4075	0.4052
Bronze Adult	0.4214	0.4040	0.4026
Catastrophic Adult	0.4209	0.4033	0.4021
Platinum Child	0.3074	0.3214	0.3345
Gold Child	0.3028	0.3164	0.3297
Silver Child	0.2990	0.3121	0.3259
Bronze Child	0.2957	0.3083	0.3223
Catastrophic Child	0.2952	0.3077	0.3217
Platinum Infant	0.3263	0.3166	0.3579
Gold Infant	0.3225	0.3126	0.3559
Silver Infant	0.3196	0.3094	0.3545
Bronze Infant	0.3181	0.3078	0.3541
Catastrophic Infant	0.3179	0.3075	0.3540

b. Overview of the Payment Transfer Formula (§ 153.320)

We previously defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment state payment transfer formula.³² Risk adjustment transfers (total payments and charges including high-cost risk pool payments and charges) are calculated after issuers have completed their risk adjustment EDGE data submissions for the applicable benefit year. The state payment transfer formula includes a set of cost adjustment terms that require transfers to be calculated at the geographic rating area level for each plan (that is, we calculate separate transfer amounts for each rating area in which a risk adjustment covered plan operates).

The risk adjustment state payment transfer formula generally calculates the difference between the revenues required by a plan, based on the health risk of the plan's enrollees, and the revenues that a plan can generate for those enrollees. These differences are then compared across plans in the state market risk pool and converted to a dollar amount based on the statewide average premium. HHS chose to use statewide average premium and normalize the risk adjustment state payment transfer formula to reflect state average factors so that each plan's

enrollment characteristics are compared to the state average and the calculated payment amounts equal calculated charges in each state market risk pool. Thus, each plan in the risk pool receives a risk adjustment payment or charge designed to compensate for risk for a plan with average risk in a budget-neutral manner. This approach supports the overall goals of the risk adjustment program, which are to encourage issuers to rate for the average risk in the applicable state market risk pool, to stabilize premiums, and to avoid the creation of incentives for issuers to operate less efficiently, set higher prices, develop benefit designs or create marketing strategies to avoid high-risk enrollees. Such incentives could arise if we used each issuer's plan's own premium in the risk adjustment state payment transfer formula, instead of statewide average premium.

In the absence of additional funding, we established, through notice and comment rulemaking,³³ the HHS-operated risk adjustment program as a budget-neutral program to provide certainty to issuers regarding risk

adjustment payments and charges, which allows issuers to set rates based on those expectations. Adopting an approach that would not result in balanced payments and charges would create considerable uncertainty for issuers regarding the proportion of risk adjustment payments they could expect to receive. Additionally, in establishing the HHS-operated risk adjustment program, we could not have relied on the potential availability of general appropriation funds without creating the same uncertainty for issuers in the amount of risk adjustment payments they could expect, or reducing funding available for other programs. Relying on each year's budget process also would have required us to delay setting the parameters for any risk adjustment payment proration rates well after the plans were in effect for the applicable benefit year. HHS also could not have relied on any potential state budget appropriations in states that elected to operate a state-based risk adjustment program, as such funds would not have been available for purposes of administering the HHS-operated risk adjustment program. Without the adoption of a budget-neutral framework, HHS would have needed to assess a charge or otherwise collect additional funds to avoid prorating risk adjustment payments. The resulting uncertainty would have also conflicted with the overall goals of the risk adjustment program—to stabilize premiums and reduce incentives for issuers to avoid enrolling individuals with higher-than-average actuarial risk.

In light of the budget-neutral framework, HHS uses statewide average premium as the cost-scaling factor in the state payment transfer formula under

³² The state payment transfer formula refers to the part of the HHS risk adjustment methodology that calculates payments and charges prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 benefit year.

³³ For example, see Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, Proposed Rule, 76 FR 41938 (July 15, 2011); Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, Final Rule, 77 FR 17232 (March 23, 2012); and the 2014 Payment Notice, Final Rule, 78 FR 15441 (March 11, 2013). Also see, the 2018 Payment Notice, Final Rule, 81 FR 94058 (December 22, 2016); and the 2019 Payment Notice, Final Rule, 83 FR 16930 (April 17, 2018). Also see the Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and the Patient Protection and Affordable Care Act; and Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year Final Rule, 83 FR 63419 (December 10, 2018).

the HHS-operated risk adjustment methodology, rather than a different parameter, such as each plan's own premium, which would not have automatically achieved equality between risk adjustment payments and charges in each benefit year. As set forth in prior discussions,³⁴ use of a plan's own premium or a similar parameter would have required a balancing adjustment in light of the program's need for budget neutrality—either reducing payments to issuers owed a payment, increasing charges on issuers assessed a charge, or splitting the difference in some fashion between issuers owed payments and issuers assessed charges. Such adjustments would have impaired the risk adjustment program's goals, as discussed previously in this proposed rule, of encouraging issuers to rate for the average risk in the applicable state market risk pool, stabilizing premiums, and avoiding the creation of incentives for issuers to operate less efficiently, set higher prices, develop benefit designs or create marketing strategies to avoid higher-risk enrollees. Use of an after-the-fact balancing adjustment is also less predictable for issuers than a methodology that is established in advance of a benefit year. Stakeholders who support use of a plan's own premium state that use of statewide average premium penalizes issuers with efficient care management. While effective care management may make a plan more likely to have lower costs,³⁵ we do not believe that the care management strategies make the plan more likely to enroll lower-than-average risk enrollees; effective care management strategies might even make the plan more likely to attract higher-than-average risk enrollees, in which case the plan would benefit from the use of statewide average premium in the state payment transfer formula in the HHS risk adjustment methodology. As noted by commenters to the 2014 Payment Notice proposed rule, transfers may also be more volatile from year to

³⁴ For example, see September 12, 2011, *Risk Adjustment Implementation Issues* White Paper, available at: https://www.cms.gov/CCIIO/Resources/Files/Downloads/riskadjustment_whitepaper_web.pdf. Also see the Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and the Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year, Final Rule, 83 FR 63419 (December 10, 2018).

³⁵ There are many reasons why an issuer could have lower-than-average premiums. For example, the low premium could be the result of efficiency, mispricing, a strategy to gain market share or some combination thereof.

year and sensitive to anomalous premiums if scaled to a plan's own premium instead of the statewide average premium. In all, the advantages of using statewide average premium outweigh the pricing instability and other challenges associated with calculating transfers based on a plan's own premium.

In the HHS risk adjustment methodology, the state payment transfer formula is designed to provide a per member per month (PMPM) transfer amount. The PMPM transfer amount derived from the state payment transfer formula is multiplied by each plan's total billable member months for the benefit year to determine the payment due to or charge owed by the issuer for that plan in a rating area. The payment or charge under the state payment transfer formula is thus calculated to balance the state market risk pool in question.

i. Accounting for High-Cost Risk Pool in the Transfer Formula

In addition to the charge or payment assessed under the state payment transfer formula for an issuer in a state market risk pool based on plan liability risk scores, in the 2018 Payment Notice, we added to the HHS-operated risk adjustment methodology additional transfers that would reflect the payments and charges assessed for the high-cost risk pool discussed above. To account for costs associated with exceptionally high-risk enrollees, we added transfer terms (a payment term and a charge term) that would be calculated separately from the state payment transfer formula in the HHS-operated risk adjustment methodology. For the 2019 benefit year, we finalized the addition of a term that reflects 60 percent of costs above \$1 million (*HRP_i*), in the total plan transfer calculation described below, and another term that reflects a percentage of premium adjustment to fund the high-cost risk pool and maintain the balance of payments and charges within the HHS-operated risk adjustment program for a given benefit year. We described in detail how these terms will be calculated in conjunction with the calculations under the state payment transfer formula for the 2019 benefit year in the 2019 Payment Notice.³⁶ We believe it is helpful to republish how these terms will be applied. Therefore, these adjustments are described in detail below along with the calculations under the state payment transfer formula.

³⁶ See 83 FR 16930 at 16954.

As discussed in detail above, for the 2020 benefit year, we are proposing to maintain the high-cost risk pool with the threshold of \$1 million and a coinsurance rate of 60 percent, and the same parameters would apply for the 2021 benefit year and beyond, unless otherwise amended through notice-and-comment rulemaking. Similar to the 2019 benefit year, we propose to add a term that reflects 60 percent of costs above \$1 million (*HRP_i*), in the total plan transfer calculation described below, and another term that reflects a percentage of premium adjustment to fund the high-cost risk pool and maintain the balance of payment and charges within the HHS-operated risk adjustment program for a given benefit year. For the 2020 benefit year, we propose to use a percentage of premium adjustment factor that would be applied to each plan's total premium amount, rather than the percentage of PMPM premium adjustment factor, consistent with the approach finalized in the 2019 Payment Notice. The percentage of premium adjustment factor applied to a plan's total premium amount results in the same adjustment as a percentage of the PMPM premium adjustment factor applied to a plan's PMPM premium amount and multiplied by the plan's number of billable member months. We propose to apply these same terms for future benefit years that maintain the same underlying parameters for the high-cost risk pool adjustment (that is, \$1 million threshold and 60 percent coinsurance rate). We seek comment on these proposals.

ii. State Flexibility Requests (§ 153.320(d))

In the 2019 Payment Notice, we provided states the flexibility to request a reduction to the otherwise applicable risk adjustment transfers calculated under the HHS-operated risk adjustment methodology, which is calibrated on a national dataset, for the state's individual, small group, or merged markets by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's market(s). We finalized that any requests received would be published in the respective benefit year's proposed notice of benefit and payment parameters, and the supporting evidence would be made available for public comment.³⁷

In accordance with § 153.320(d)(2), beginning with the 2020 benefit year, states must submit such requests with the supporting evidence and analysis

³⁷ 2019 Payment Notice Final Rule, 83 FR 16930 (April 17, 2018) and 45 CFR 153.320(d)(3).

outlined under § 153.320(d)(1) by August 1st of the calendar year that is 2 calendar years prior to the beginning of the applicable benefit year.

In this rule, we propose to amend § 153.320(d)(3) to add language to provide that if the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the HHS Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will do so, making available on the CMS website only the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information. Similar to the rate review program established under section 2794 of the PHS Act, under this proposal, HHS would release only information that is not a trade secret or confidential commercial or financial information as defined under the HHS FOIA regulations.³⁸ In these circumstances, similar to the federal rate review requirements, we propose that the states requesting a reduction would need to provide a version for public release that redacts the trade secret and confidential commercial or financial information as defined under the HHS FOIA

regulations, while also providing an unredacted version to HHS for its review of the state's reduction request. We also propose that state requests for individual market risk adjustment transfers reduction would be applied to both the catastrophic and non-catastrophic individual market risk pools, unless state regulators request otherwise.

We seek comment on these proposals.

For the 2020 benefit year, HHS received a request to reduce risk adjustment transfers for the Alabama small group market by 50 percent. Alabama's request states that the presence of a dominant carrier in the small group market precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The state regulators stated that their review of the risk adjustment payment issuers' financial data suggested that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the small group market for the 2020 benefit year would not exceed 1 percent, the de minimis premium increase threshold set forth in the 2019 Payment Notice. We seek comment on this request to reduce risk adjustment transfers in the Alabama small group

market by 50 percent for the 2020 benefit year. The request and additional documentation submitted by Alabama are posted under the "State Flexibility Requests" heading at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html>.

iii. The Payment Transfer Formula

Although the proposed HHS payment transfer formula for the 2020 benefit year is unchanged from what was finalized in the 2019 Payment Notice (83 FR 16954 through 16961), we believe it is useful to republish the formula in its entirety in this proposed rule. Additionally, we are republishing the description of the administrative cost reduction to the statewide average premium and high-cost risk pool factors that we previously described in the 2019 Payment Notice although these factors remain unchanged in this proposed rule.³⁹ Transfers (payments and charges) under the state payment transfer formula would be calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. The state payment transfer calculation that is part of the HHS risk adjustment payment transfer formula is:

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)} \right] \bar{P}_s$$

Where:

\bar{P}_s = Statewide average premium;
 $PLRS_i$ = plan i 's plan liability risk score;
 AV_i = plan i 's metal level AV;
 ARF_i = allowable rating factor;
 IDF_i = plan i 's induced demand factor;
 GCF_i = plan i 's geographic cost factor;
 s_i = plan i 's share of state enrollment.

The denominator would be summed across all risk adjustment covered plans in the risk pool in the market in the state.

The difference between the two premium estimates in the state payment transfer formula determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment. The value of the plan average risk score by itself does not determine whether a plan would be assessed a charge or receive a payment—even if the risk score is greater than 1.0, it is possible that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating (as

measured through the allowable rating factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers under the state payment transfer formula are calculated at the risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of the risk adjustment state payment transfer calculations.⁴⁰ This resulting PMPM plan payment or charge would be multiplied by the number of billable member months to determine the plan payment or charge based on plan liability risk scores for a plan's geographic rating area for the risk pool market within the state.

We previously defined the cost scaling factor, or the statewide average premium term, as the sum of the average premium per member month of plan i (P_i) multiplied by plan i 's share of statewide enrollment in the market risk pool (s_i). The statewide average premium would be adjusted to remove

a portion of the administrative costs that do not vary with claims (14 percent) as follows:

$$\bar{P}_s = (\sum_i (s_i \cdot P_i)) * (1 - 0.14) = (\sum_i (s_i \cdot P_i)) * 0.86$$

Where:

s_i = plan i 's share of statewide enrollment in the market in the risk pool;
 P_i = average premium per member month of plan i .

The high-cost risk pool adjustment amount would be added to the state payment transfer formula to account for: (1) The payment term, representing the portion of costs above the threshold reimbursed to the issuer for high-cost risk pool payments (HRP_i), if applicable; and (2) the charge term, representing a percentage of premium adjustment, which is the product of the high-cost risk pool adjustment factor ($HRPC_m$) for the respective national high-cost risk pool m (one for the individual market, including catastrophic, non-catastrophic

individual market for purposes of the national high-cost risk pool payment and charge calculations.

³⁸ See 45 CFR 154.215(h)(2).

³⁹ See 83 FR 16930 at 16960.

⁴⁰ As detailed elsewhere in this proposed rule, catastrophic plans are considered part of the

and merged market plans, and another for the small group market), and the plan's total premiums (TP_i). For this calculation, we would use a percent of premium adjustment factor that is applied to each plan's total premium amount.

The total plan transfers for a given benefit year would be calculated as the product of the plan PMPM's transfer amount (T_i) multiplied by the plan's billable member months (M_i), plus the high-cost risk pool adjustments. The total plan transfer (payment or charge) amounts under the HHS risk adjustment payment transfer formula would be calculated as follows:

$$\text{Total transfer}_i = (T_i \cdot M_i) + \text{HRP}_i - (\text{HRPC}_m \cdot TP_i)$$

Where:

Total Transfer_i = Plan i 's total HHS risk adjustment program transfer amount;
 T_i = Plan i 's PMPM transfer amount based on the state transfer calculation;
 M_i = Plan i 's billable member months;
 HRP_i = Plan i 's total high-cost risk pool payment;
 HRPC_m = High-cost risk pool percent of premium adjustment factor for the respective national high-cost risk pool m ;
 TP_i = Plan i 's total premium amounts.

As we noted above, we received a request to reduce transfers in the Alabama small group market by 50 percent for the 2020 benefit year. If the request is approved and finalized by HHS for the 2020 benefit year, the approved reduction percentage would be applied to the plan PMPM payment or charge transfer amount (T_i) under the state payment transfer calculation for the Alabama small group market risk pool. This potential reduction to the PMPM transfer amounts is not shown in the HHS risk adjustment state payment transfer formula above.

c. Risk Adjustment Issuer Data Requirements (§§ 153.610, 153.710)

In the 2018 Payment Notice,⁴¹ we finalized the collection of masked enrollee-level data from issuers' EDGE servers (referred to as "enrollee-level EDGE data") beginning with the 2016 benefit year to recalibrate the risk adjustment models and inform development of the AV Calculator and methodology.

In the 2018 Payment Notice, we also stated that we would consider using this enrollee-level EDGE data in the future for calibrating other HHS programs in the individual and small group markets, and to produce a public use file to help governmental entities and independent researchers better understand these markets. We noted that a public use file

derived from these data would be de-identified in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements, would not include proprietary issuer or plan identifying data, and would adhere to HHS rules and policies regarding protected health information (PHI) and personally identifiable information (PII). We also described in guidance the data elements in the enrollee-level EDGE dataset and the data elements proposed to be made available for research requests.⁴²

Under the HIPAA safe harbor for de-identification of data at 45 CFR 164.514(b)(2), public use files are considered de-identified if they exclude 18 specific identifiers that could be used alone or in combination with other information to identify an individual who is a subject of the information. To make the enrollee-level EDGE data available as a public use file that comports with the requirements of § 164.514(b)(2), we would have to remove dates (other than the year) and ages for enrollees ages 90 or older.⁴³ Commenters have stated that the public use file would be limited in its usefulness because it excludes dates that would be useful to conduct health services research. A limited data set, as defined at § 164.514(e)(2), may include dates, which could enable requestors to do analyses they would not be able to with a public use file. We believe entities seeking to use the enrollee-level EDGE data would be able to better understand the individual and small group markets with a limited data set.

Thus, we propose to create and make available by request a limited data set file rather than a public use file, as we believe a limited data set file would be more useful to requestors for research, public health, or health care operations purposes. Under this proposal, if finalized, we would make enrollee-level EDGE data, beginning with the 2016 benefit year EDGE data, available as a "Limited Data Set" file under § 164.514(e). This limited data set file would not include the direct identifiers of the individual or of relatives, employers, or household members of the individual, which are required to be removed under the limited data set definition at § 164.514(e)(2), as issuers do not submit these identifiers to their EDGE servers. We also propose to limit disclosures of the limited data set to

⁴² Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Enrollee-level-EDGE-Dataset-for-Research-Requests-05-18-18.pdf>.

⁴³ HHS does not currently collect any of the other 18 identifiers under 45 CFR 164.514(b)(2) that would require de-identification.

requestors who seek the data for research, public health, or health care operations purposes, as those terms are defined under § 164.501, as is done with other limited data sets made available by HHS. We would require qualified requestors to sign a data use agreement to ensure the data will be maintained, used, and disclosed only as permitted under the HIPAA Privacy Rule, and to ensure that any inappropriate uses or disclosures are reported to HHS. HHS components would also be able to request the limited data set file for research, public health, or health care operations purposes, as those terms are defined under § 164.501. We also clarify that, if this proposal is finalized, we would make a limited data set file available on an annual basis, reflecting enrollee-level data from the most recent benefit year available on EDGE servers. If this proposal is finalized, we would not offer a public use file based on the enrollee-level EDGE data. We seek comment on this proposal.

In addition, we received comments in response to the guidance describing the data elements to be made available as part of the public use file for research requests⁴⁴ noting that researchers would benefit from additional data elements on enrollees' geographic identifiers, enrollees' income level, provider identifier, provider's geographic location, internal claim identifier, enrollees' plan benefit design details, and enrollees' out-of-pocket costs by cost-sharing type (deductible, coinsurance, and copayment). We began collecting a claim identifier to associate all services rendered under the same claim beginning with the 2017 benefit year enrollee-level EDGE data.

Therefore, if the proposal to make a limited data set is finalized, we would be able to include this grouped claims identifier beginning for the 2017 benefit year enrollee-level EDGE limited data set file. However, regarding the other data elements commenters requested, either issuers do not submit them to their EDGE servers, or we currently do not extract them from issuers' EDGE servers due to concerns about the ability to use the data element(s) to identify issuers or plans. For example, issuers do not currently submit data to their EDGE servers on enrollees' plan benefit design, specific cost-sharing elements (deductibles, copayments), provider identifiers or providers' geographic location, enrollees' income level or enrollees' geographic location more

⁴⁴ Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Enrollee-level-EDGE-Dataset-for-Research-Requests-05-18-18.pdf>.

⁴¹ See 81 FR 94058 at 94101.

specific than the rating area, and therefore, we are unable to extract such information as part of the enrollee-level EDGE data. However, issuers do submit enrollees' state and rating areas as part of the EDGE server submissions, making it possible to extract these elements from the issuers' EDGE servers as part of the enrollee-level EDGE data. If we were to extract state and rating areas, we could also make such details available as part of the proposed enrollee-level EDGE limited data set file. We continue to believe the enrollee-level EDGE data can increase cost transparency for consumers and stakeholders for the individual and small group markets and can be a useful resource for government entities and independent researchers to better understand these markets. We also recognize access and use of enrollee-level EDGE data should continue to safeguard enrollee privacy and security and issuers' proprietary information. Based on the comments received, we are seeking comment on whether to extract state and rating area information for enrollees as part of the enrollee-level EDGE data. As noted previously, we use the enrollee-level EDGE data to recalibrate the risk adjustment models and inform development of the AV Calculator and methodology. Extracting additional state and rating area information could enable HHS to assess the impact of differences in geographic factors in the HHS risk adjustment methodology. In addition, stakeholders have noted that adding geographic elements to the AV Calculator would better estimate the AV of plans based on the cost differences across regions. Extraction of these geographic details (state and rating area) from issuers' EDGE servers could also help support other HHS programs and policy priorities, as well as provide additional data elements for researchers. We note that although these geographic data elements are not currently extracted from the enrollee-level EDGE dataset, extracting them will not increase burden for issuers, as issuers already submit these data elements as part of the EDGE server data submission process. We seek comment on how these data elements could be used in the HHS-operated risk adjustment program, AV Calculator and methodology, and other HHS programs in the individual and small group (including merged) markets, as well as on how these data elements could benefit researchers and public health. If we were to extract state and rating area information, we would do so as part of the enrollee-level EDGE data extraction and would use this information to support the recalibration

and policy development related to the HHS-operated risk adjustment program, the AV Calculator and methodology, as well as other HHS programs in the individual and small group (including merged) markets. We also seek comment on if we were to extract these data elements, whether to make state and rating area information available as part of the proposed limited data set that would be made available to qualified requestors. We seek comment on the advantages and disadvantages of using state and rating area information for recalibration of the HHS-operated risk adjustment program, the AV Calculator and methodology, and other HHS individual and small group (including merged) market programs. We seek specific comments on possible research purposes for these data elements, whether the benefits of extracting these additional data elements outweigh the potential risk to issuers' proprietary information, and whether extraction of this data is consistent with the goals of a distributed data environment. We reiterate that these data would not include direct identifiers of an individual or of relatives, employers, or household members of the individual, as issuers do not submit these elements to their EDGE servers, and qualified requestors would be required to sign a data use agreement to ensure the data would be maintained, used, and disclosed only as permitted under the HIPAA Privacy Rule. We also seek specific comment on the other data elements outlined above that commenters requested be part of the enrollee-level EDGE dataset, but that issuers do not currently submit to their EDGE servers, and other enrollment and claims data elements not otherwise described above, and whether collection of such data elements could benefit the calibration of the HHS risk adjustment program, the AV calculator and methodology, and other HHS individual and small group (including merged) markets programs. We also seek specific comment with examples on whether other data elements that issuers do not currently submit to their EDGE servers could benefit further research, public health or health care operations as part of a limited data set file made available to qualified requestors.

In addition, we propose to extend the use of enrollee-level EDGE data and reports extracted from issuers' EDGE servers (including data reports and ad hoc querying tool reports) to calibrate and operationalize our individual and small group (including merged) market programs (for example, the HHS-operated risk adjustment program, the

AV calculator and methodology, and the out-of-pocket calculator), as well as to conduct policy analysis for the individual and small group (including merged) markets (for example, to assess the market impacts of policy options being deliberated). We believe these additional uses of the enrollee-level EDGE data will enhance our ability to develop and set policy for the individual and small group (including merged) markets and avoid burdensome data collections from issuers.

d. Risk Adjustment User Fee for 2020 Benefit Year (§ 153.610(f))

As noted above, if a state is not approved to operate, or chooses to forgo operating its own risk adjustment program, HHS will operate a risk adjustment program on its behalf. For the 2020 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice,⁴⁵ HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. Section 153.610(f)(2) provides that an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

OMB Circular No. A-25R established federal policy regarding user fees, and specified that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(B) of Circular No. A-25R to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection. The risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

In the 2019 Payment Notice,⁴⁶ we calculated the federal administrative expenses of operating the risk adjustment program for the 2019 benefit year to result in a risk adjustment user fee rate of \$1.80 per billable member per year or \$0.15 PMPM, based on our estimated contract costs for risk adjustment operations, estimates of billable member months for individuals

⁴⁵ See 78 FR 15409 at 15416.

⁴⁶ 83 FR 16930 at 16972.

enrolled in a risk adjustment covered plan, and eligible administrative and personnel costs related to the administration of the HHS-operated risk adjustment program. For the 2020 benefit year, we propose to generally use the same methodology to estimate our administrative expenses to operate the program, with the modifications described below. These costs cover development of the risk adjustment models and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, operational support, and administrative and personnel costs dedicated to risk adjustment activities related to the HHS-operated program. To calculate the user fee, we divided HHS's projected total costs for administering the risk adjustment program by the expected number of billable member months in risk adjustment covered plans in the 50 states and the District of Columbia where HHS will operate risk adjustment for the 2020 benefit year.

We estimate that the total cost for HHS to operate the risk adjustment program for the 2020 benefit year would be approximately \$50 million, and the risk adjustment user fee would be \$2.16 per billable member per year, or \$0.18 PMPM. The updated cost estimates attribute all costs related to the EDGE server data collection and data evaluation (quantity and quality evaluations) activities to the risk adjustment program rather than sharing them with the reinsurance program, which is no longer operational.⁴⁷ In addition, we previously collected amounts under the reinsurance program for administrative expenses related to that program, which partially funded contracts that were used for both the risk adjustment and reinsurance programs. We no longer allocate indirect costs for personnel or administrative costs to the reinsurance program, and are reflecting the full value of those costs as part of risk adjustment operations for the 2020 benefit year. The risk adjustment user fee costs are also estimated to be slightly higher due to increased contract costs based on additional activities for the risk adjustment data validation program development and execution, including

updated cost estimates associated with the non-pilot years of the risk adjustment data validation program, including estimates for error rate adjustments, development of the new risk adjustment data validation audit tool, and additional contractor support for risk adjustment data validation discrepancies and appeals. The estimated costs also incorporate the full personnel and administrative costs associated with risk adjustment program development and operations in the risk adjustment user fee for the 2020 benefit year. The personnel and administrative costs included in the calculation of the 2019 benefit year risk adjustment user fee for the 2019 Payment Notice final rule incorporated only a portion of the personnel costs, and excluded indirect costs. The proposed 2020 benefit year risk adjustment user fee includes the full amount for eligible personnel costs, as well as eligible indirect costs. Finally, we estimate individual and small group market billable member months for the 2020 benefit year to remain roughly the same, as observed in the most recent risk adjustment data available for the 2017 benefit year. We seek comment on the proposed risk adjustment user fee for the 2020 benefit year.

3. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

We conduct risk adjustment data validation under §§ 153.630 and 153.350 in any state where HHS is operating risk adjustment on a state's behalf, which for the 2020 benefit year is all 50 states and the District of Columbia. The purpose of risk adjustment data validation is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and proper functioning of the HHS-operated risk adjustment program. Risk adjustment data validation consists of an initial validation audit and a second validation audit. Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation auditor. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to its initial validation auditor for data validation. Each issuer's initial validation audit is followed by a second validation audit, which is conducted by an entity HHS retains to verify the accuracy of the findings of the initial validation audit. Set forth below are proposed amendments and clarifications to the risk adjustment data validation program in light of experience and feedback from

issuers during the first 2 pilot years of the program.

a. Varying Initial Validation Audit Sample Size (§ 153.630(b))

In the 2014 Payment Notice, we established the risk adjustment data validation program that HHS uses when operating risk adjustment on behalf of a state. Consistent with § 153.350(a), HHS is required to ensure proper validation of a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that state. The current enrollee sample size selected for the initial validation audit is 200 enrollees statewide (that is, combining an issuer's individual, small group, and merged market enrollees (as applicable) in risk adjustment covered plans in the state) for each issuer's Health Insurance Oversight System (HIOS) ID, based on sample size precision analyses we conducted using proxy data from the Medicare Advantage program. Those analyses calculated a range of sample sizes to target a 10 percent precision at a 95 percent confidence level. The resulting range of sample sizes were between 100 and 300, and we selected 200 as a midpoint.⁴⁸ In the 2015 Payment Notice, we stated that, after the initial years of risk adjustment data validation, we would evaluate our sampling assumptions using actual enrollee data and consider using larger sample sizes for issuers that are larger or have higher variability in their enrollee risk score error rates, and smaller sample sizes for issuers that are smaller or have lower variability in their enrollee risk score error rates. We also stated that we would use our sampling experience in the initial years of risk adjustment data validation to evaluate using issuer-specific sample sizes.

Additionally, in the initial years of risk adjustment data validation, we constrained the "10th stratum" of the initial validation audit sample—that is, enrollees without HCCs selected for the initial validation audit sample—to be one-third of the sampled initial validation audit enrollees. Under the current approach, the remaining 9 age-risk strata are selected using a Neyman allocation⁴⁹ which optimizes the number of enrollees per stratum for the remaining two-thirds of sampled

⁴⁸ See 79 FR 13743 at 13756.

⁴⁹ Neyman allocation is a method to allocate samples to strata based on the strata's variances and similar sampling costs in the strata. A Neyman allocation scheme provides the most precision for estimating a population mean given a fixed total sample size. See <http://methods.sagepub.com/reference/encyclopedia-of-survey-research-methods/n324.xml>.

⁴⁷ Although the 2016 benefit year was the final benefit year for the reinsurance program, close-out activities continued in the 2018 fiscal year, including the collection of the second part of the 2016 benefit year contributions for contributing entities that elected the bifurcated schedule, which were due by November 15, 2017, and are expected to continue in the 2019 fiscal year.

enrollees. Because we expected enrollees without HCCs to make up the majority of issuers' enrollees, in the absence of data from the individual and small group markets, we constrained stratum 10 to ensure that healthy enrollees were sampled in the initial years of risk adjustment data validation to establish adequate sampling assumptions.

In this proposed rule, we propose to extend the Neyman allocation sampling methodology to also include the 10th stratum of enrollees without HCCs, such that samples would be assigned to all 10 strata using a Neyman allocation. Since a Neyman allocation approach is expected to provide a more optimal sample size allocation, we believe that using the Neyman allocation for all strata would optimize issuers' initial validation samples and yield better precision than the one-third/two-thirds approach currently used in the enrollee initial validation audit sample. Further, an approach that permits for a larger portion of the sample to be allocated to the HCC strata as compared to the two-thirds allocation used in the current approach would result in a more robust HCC sample in support of the measurement of HCC failure rates under the HCC failure rate methodology finalized in the 2019 Payment Notice. Finally, it would increase the probability of achieving our original target of 10 percent precision based on our historical observations of greater error rate variances among the HCC strata. We seek comment on this proposal to extend the Neyman allocation sampling methodology to the 10th stratum of enrollees without HCCs.

As previously discussed, the current initial validation audit sample size of 200 was selected to achieve an estimated 10 percent precision, assuming a distribution of risk score errors similar to that found in the Medicare Advantage risk adjustment data validation program. However, since the HCC group failure rate approach to error estimation (referred to as the HCC failure rate methodology) will be implemented beginning with the 2017 benefit year of risk adjustment data validation, we anticipate that the calculated precision will differ from the estimate we used, which was based on the Medicare Advantage error rate data. Therefore, beginning with the 2019 benefit year of risk adjustment data validation,⁵⁰ we propose to vary the initial validation audit sample size based on issuer characteristics, such as

issuer size and prior year HCC failure rates. We are considering, and seek comment on, several different approaches for varying the initial validation audit sample size. We note that HHS will not increase the sample above 200 enrollees when it performs the second validation audit pairwise means test because a 200 enrollee sample will be sufficient to achieve statistical significance in that test. If we finalize an approach that incorporates the use of prior year HCC failure rates, we propose to use the 2017 benefit year risk adjustment data validation results—the only year of risk adjustment data validation results used for transfer adjustments that will be available at that time—as an initial basis for determining the 2019 benefit year initial validation audit samples. The 2017 risk adjustment data validation program year will also be the first year in which the audit results will impact risk adjustment risk scores and subsequently, risk adjustment transfers. Thus, we recognize there is considerable uncertainty in adopting a proposal to adjust sample sizes based on HCC failure rates where we do not yet have experience with risk adjustment data validation transfer data (that is, using HCC failure rate results to adjust risk scores that affect risk adjustment transfers). To account for the possibility of large variation in HCC failure rates in 2017 risk adjustment data validation results, we propose to increase the precision of initial validation audit samples above 200 enrollees for issuers with lower or higher-than-average failure rates that are not precisely measured, as described further below. We also propose to require a minimum sample size of 400 enrollees for each larger issuer (defined as an issuer with 50,000 or more enrollees calculated statewide based on the benefit year being validated) with lower or higher-than-average failure rates that are not precisely measured, as we believe that larger issuers have the capability to absorb the increased burden and validate larger samples and represent a greater part of the risk pool, such that having any risk score adjustments resulting from risk adjustment data validation would have a greater impact on overall risk adjustment transfers. We solicit comment on this proposed approach, particularly with regard to the benefit year that we should use to calculate issuers' enrollment for the applicable risk adjustment data validation benefit year.

We also seek comment on whether we should finalize an approach that uses HCC failure rates to determine sample

size, and whether HHS should use the latest available benefit year HCC failure rate results alone, or use multiple prior years' HCC failure rates when determining an issuer's sample size. Under this proposed approach, we would also vary sample size based on issuers' sample precision for issuers with HCC failure rates close to the threshold that determines whether an issuer will have a transfer adjustment. Of the issuers outside of a confidence interval threshold around the mean HCC failure rates by HCC group, we would maintain the current minimum sample size of 200 enrollees for smaller issuers (defined as issuers with between 3,000 and 49,999 enrollees calculated statewide based on the benefit year being validated), with sample sizes increasing for issuers in this cohort with poor precision. For larger issuers (that is, those with 50,000 or more enrollees calculated statewide based on the benefit year being validated), we propose to establish a minimum sample size of 400 enrollees, with sample sizes increasing for issuers with poor precision. For very small issuers (defined as issuers with below 3,000 enrollees calculated statewide based on the benefit year being validated), we propose to maintain a sample size of 200 enrollees regardless of the issuer's measured precision.

We are also considering an alternative approach to adjusting sample size that would increase sample sizes based on issuer size alone, and would continue to use the proxy Medicare Advantage risk score error rate data for the accompanying precision analyses. Additionally, we solicit comment on whether the issuers' enrollment should be calculated based on the year that is being validated or based on the benefit year in which the HCC failure occurred.

Additionally, in response to a comment we received on the 2019 Payment Notice that larger sample sizes could improve the accuracy of issuers' risk adjustment data validation samples, we solicit comment on whether to permit issuers of any size and HCC failure rate to request a larger sample size before the applicable benefit year's initial validation audit commences. Regardless of an issuer's sample size, all issuers would be required to adhere to the same risk adjustment data validation timelines such that data validation activities related to the same benefit year occur at the same time, regardless of the issuer's sample size. We also request comment on whether this potential flexibility for issuers to determine their initial validation audit sample size necessitates any changes to the second validation audit pairwise

⁵⁰ Activities related to the 2019 benefit year risk adjustment data validation generally begin in the second quarter of 2020 calendar year.

means test, as well as on safeguards that can help ensure that the collection of larger amounts of enrollee data does not increase privacy risks for consumers.

A discussion of the options we are considering to vary the initial validation audit sample size, including certain advantages and disadvantages for each, follows below. We solicit comment on all of these proposals.

i. Varying Sample Size Based on HCC Failure Rates, Sample Precision, and Issuer Size

One approach we are considering would vary sample size based on a combination of the following issuer characteristics: HCC failure rates, sample precision, and issuer size. As stated above, we would use the 2017 risk adjustment data validation results as an initial basis for determining 2019 initial validation audit sample sizes. We would increase the precision of initial validation audit samples above 200 enrollees for issuers with lower or higher than average HCC failure rates that are not precisely measured, as described further below. For issuers with average HCC failure rates, the initial validation audit sample size would remain at 200 enrollees.

Under this approach, we would adjust sample sizes above the applicable baseline sample size of 200 only for issuers who are more than 1.644 standard deviations away from the mean for any HCC failure rate group. This targeted sampling adjustment would ensure that all issuers outside or just inside of the HCC failure rate outlier threshold (1.96 standard deviations) receive sample sizes that better meet our targeted precision, that issuers receiving error rates are in fact outliers, and that issuers that did not receive an error rate, but had higher-than-average HCC failure rates, were not false negatives due to low precision in their sample. Issuers in this cohort whose sample size does not meet the targeted precision would have their initial validation audit sample size adjusted above 200 enrollees to more closely achieve the targeted precision level.

Issuers with HCC failure rates within 1.644 standard deviations of the mean for all HCC failure rate groups would

have initial validation audit sample sizes of 200 enrollees, as we do not believe a larger sample size would result in a meaningful impact on the error rates for these issuers. By including issuers with HCC failure rates above 1.644 standard deviations from the mean, but who were not outliers (above 1.96 standard deviations from the mean), the sampling approach would take into account issuers that were not identified as outliers under the HCC failure rate methodology, but may have been outliers with a larger sample size. By expanding these issuers' sample sizes and outlier issuers' sample sizes where issuers' initial sample precision did not meet the targeted value, we can evaluate a more accurate representation of those issuers' populations by capturing more enrollees to better reflect the variation in an issuer's population in the next year of risk adjustment data validation. The proposed use of 1.644 standard deviations (a 90 percent confidence interval) would ensure that we are evaluating the sampling precision of approximately 10 percent of issuers, to assess the potential for false positives or false negatives around the approximate 5 percent of issuers identified as outliers by HCC failure rate group using 1.96 standard deviations (a 95 percent confidence interval).

This proposal is consistent with the approach used for error estimation under the HCC failure rate methodology that will be used beginning with the 2017 benefit year risk adjustment data validation, and would reduce the aggregate issuer burden associated with an increased sample size by only affecting outlier issuers and those issuers that are slightly inside of the 1.96 standard deviations from the mean outlier threshold—that is, issuers with HCC failure rates results that affect or potentially affect transfer adjustments. This approach considers issuers that are closer to the mean to have samples that are of an appropriate precision level, and thus would have the effect of most issuers' (approximately 90 percent) samples remaining unchanged from the current baseline sample size of 200.

For smaller issuers (those with between 3,000 and 49,999 enrollees calculated statewide based on the

benefit year being validated) outside of 1.644 standard deviations from the mean of any HCC failure rate group, we propose starting with a minimum sample size of 200 enrollees equivalent to the initial validation audit sample size that will be used for 2018 risk adjustment data validation, which will increase based on the issuer's measured precision. For larger issuers (those with 50,000 or more enrollees calculated statewide based on the benefit year being validated) that are outside of 1.644 standard deviations from the mean of any HCC failure rate group, we propose starting with an initial validation audit sample size of 400 enrollees, which would similarly increase based on the issuer's measured precision. For very small issuers (defined for this purpose as issuers with below 3,000 enrollees calculated statewide based on the benefit year being validated) outside of 1.644 standard deviations from the mean of any HCC failure rate group, we propose to maintain the sample size at 200 enrollees. We are not proposing to increase the sample size for very small issuers because the current 200 enrollee sample size is already statistically significant for issuers with fewer than 3,000 enrollees (calculated statewide based on the benefit year being validated), and any further sample size increase would be especially burdensome for these issuers. We propose to use the Neyman allocation for the allocation of enrollees to all 10 strata,⁵¹ if the above accompanying proposal to extend the Neyman allocation sampling methodology to also include the 10th stratum of enrollees without HCCs is finalized.

To determine the precision of the sample of group failure rates, we would estimate the absolute precision at a 95 percent confidence level using the formula below.

⁵¹ As noted previously in this proposed rule, Neyman allocation is a method to allocate samples to strata based on the strata's variances and similar sampling costs in the strata. A Neyman allocation scheme provides the most precision for estimating a population mean given a fixed total sample size. See <http://methods.sagepub.com/reference/encyclopedia-of-survey-research-methods/n324.xml>.

$$\text{Absolute Precision } (\hat{x}) = 1.96 * \widehat{SE}(\hat{x})$$

When estimating HCC group failure rate percentages, assuming a normal distribution of HCC group failure rates, precision would be calculated as follows, where $(\widehat{SE}(\widehat{GFR}_t^G))$ is the standard error of the HCC group failure rate:

$$\text{Precision } (\widehat{GFR}_t^G) = 1.96 * \widehat{SE}(\widehat{GFR}_t^G)$$

The standard error, and thus, precision, is inversely proportional to the square root of the sample size (n). Therefore, as the sample size increases, the standard error which is the metric

to measure precision would decrease (better precision would be achieved, as lower values of the precision measurement indicate a better precision). The proposed approach to

calculate the new sample size reflects the inverse relationship between the precision and the sample size, as illustrated in the formula below:

$$n_{new} = \left(\frac{\sqrt{n_{initial}} * Precision_{from_initial}}{Precision_{new_target}} \right)^2$$

Substituting the values for the original sample size and the precision target yields:

$$n_{new} = \left(\frac{\sqrt{200} * Precision_{from_initial}}{0.1} \right)^2$$

In the summer of 2019, once we have 2017 benefit year risk adjustment data validation HCC failure rates, we will be able to develop the relative precision of the sample; however, at this time, we cannot definitively determine the sample sizes that would result from this proposed approach. Because we propose using 1.644 standard deviations (a 90 percent confidence interval) to identify issuers for sampling adjustments, we estimate that approximately 55 issuers would have their sample size increased under this approach out of the approximately 500 issuers expected to participate in risk adjustment data validation for the 2019 benefit year. Using the results of 2016 risk adjustment data validation, we expect that approximately 40 larger issuers would have their sample sizes increased to at least 400 enrollees, and approximately 5 of these larger issuers would have their sample sizes increased above 400 enrollees as a result of poor sample precision. For the remaining 30 smaller issuers, we expect that approximately 50 percent would have sample precision that meets or is better than the target 10 percent precision and therefore would maintain a sample size

of 200 enrollees, with the majority of the other 15 smaller issuers facing moderate sample size increases to improve the precision of their samples. Based on our analysis of 2016 risk adjustment data validation, we believe that under this proposed approach, only a very small number of the subset of issuers outside 1.644 standard deviations from the mean HCC failure rate with poor precision (for example, precision greater than 20 percent) could have sample sizes up to 500 enrollees for smaller issuers and up to 800 for larger issuers.

For smaller issuers with HCC failure rates above 1.644 standard deviations of the mean HCC group failure rates, and an assumed precision above the 10 percent target, we estimate approximate sample size ranges for issuer precision groups below:

- Issuers with 10 percent precision or lower.
- ++ 2019 approximate sample size: 200
- Issuers with precision between 10 percent and 20 percent.
- ++ 2019 approximate sample size range: 250 to 350
- Issuers with precision above 20 percent.

++ 2019 approximate sample size range: 400 to 500

As stated above, we believe that larger samples for larger issuers allows for increased samples for issuers that have the capability to undertake the increased burden and whose errors will have a greater impact on the state market risk pool, which may also help to inform our future sampling methodology. As a result, we are proposing baseline minimum sample sizes of 400 enrollees for larger issuers with HCC failure rates above 1.644 standard deviations of the mean HCC group failure rates. For larger issuers with HCC failure rates above 1.644 standard deviations of the mean HCC group failure rates, and an assumed precision above the 10 percent target, we estimate approximate sample size ranges for issuer precision groups below:

- Issuers with 10 percent precision or lower.
- ++ 2019 approximate sample size: 400
- Issuers with precision between 10 percent and 20 percent.
- ++ 2019 approximate sample size range: 450 to 650

- Issuers with precision above 20 percent.

++ 2019 approximate sample size range: 700 to 800

We believe that increasing issuer sample sizes would provide more data that HHS could use to further refine risk adjustment data validation error rate assumptions and precision rate targets for future risk adjustment data validation. Additionally, we believe that any increase in burden would be outweighed by the increased accuracy and precision of the risk adjustment data validation results which are used to adjust risk adjustment transfers.

We request comment on the approach for determining sample sizes for very small issuers, smaller issuers, and larger issuers based on HCC failure rates and sample precision described above, and any alternative approaches that could limit burden for smaller and medium size issuers while achieving our target precision. We also request comment on whether larger issuers with over 50,000 enrollees (calculated statewide based on the benefit year being validated) should have larger initial sample sizes, as well as alternative approaches that would provide HHS with data it could use to further refine risk adjustment data validation error rate assumptions while also limiting unnecessary burdens for these issuers.

ii. Varying Initial Validation Audit Sample Size Based Only on Issuer Size

An alternative approach we are considering would increase the sample sizes based on issuer size only and continue to use the proxy Medicare Advantage risk score error rate data for conducting precision analyses. Larger sample sizes provide more opportunity to test variance in an issuer's population as compared to the current sampling method, which samples 200 enrollees regardless of the size of the issuer. The use of larger sample sizes based on issuer size could allow HHS to better ensure confidence in the risk adjustment data validation process while increasing the financial and administrative burden on issuers proportionally to their size. As noted above, larger issuers have the capability to undertake the increased burden, and their errors will have a greater proportional impact on the state market risk pool. If we were to modify sample size based on issuer size alone, we propose to develop sample sizes based on issuer size for four groups using the total number of unique enrollees in risk pools across all states where the issuer is subject to risk adjustment transfers (that is, combining enrollment for all

risk pools where the issuer offers risk adjustment covered plans, except for states where there is only one issuer in the risk pool). Under this proposed approach, HHS would use an issuer's population size for an applicable benefit year of risk adjustment to determine the issuer size group for the same benefit year of risk adjustment data validation sampling. The sample sizes would apply to all issuers in the applicable size category, without regard to their HCC failure rates or sample precision. Under this option, we would use the following groupings calculated based on the issuer's total number of enrollees in all risk pools receiving risk adjustment transfers in the applicable benefit year of risk adjustment:

- Issuers with 51–3,000 enrollees.⁵²
- ++ 2019 approximate sample size for small issuers: 90
- Issuers with 3,001–20,000 enrollees.
- ++ 2019 approximate sample size for medium issuers: 250
- Issuers with 20,001–100,000 enrollees.
- ++ 2019 approximate sample size for large issuers: 400
- Issuers with 100,001 and above.
- ++ 2019 approximate sample size for extra-large issuers: 500

Enrollment in risk pools where there are no risk adjustment transfers (that is, where there is only a single issuer) would be excluded from this calculation. We note that, under this approach, larger samples would be required for most issuers. However, we believe that any increase in burden would be outweighed by the increased precision of the risk adjustment data validation results which are used to adjust risk adjustment risk scores and subsequently risk adjustment transfers.

While this approach is the most predictable for issuers, based on HHS's analysis of increasing the sample size based on issuer size, we do not believe this is the best approach, as it would increase burden while not meaningfully improving precision for issuers with large variances in HCC failure rates or error rates. This approach also would unnecessarily increase sample sizes for issuers with good precision using a sample of 200 due to low variability in HCC failure rates or risk score errors.

⁵² Our assumption is that most issuers with fewer than 50 enrollees are likely exempt from participating in risk adjustment data validation for the benefit year because the issuer has less than 500 billable member months, but if an issuer has more than 500 billable member months and less than 50 enrollees, the issuer would still be required to participate in risk adjustment data validation in a given benefit year. For those issuers, the sample size would remain the same as prior years.

Notwithstanding these disadvantages, we acknowledge that varying the sample size using issuer size is the only way to incorporate the most current issuers' characteristics in the sample size determination, as the use of issuers' risk score errors or HCC failure rates would be based on prior years for a future initial validation sample.

We seek comment on this alternative approach. Additionally, if we finalize an approach that adjusts initial validation audit samples using issuers' size only, we request comment on whether to further subdivide each of the issuer size groups outlined above, and seek comment on what the characteristics and number of subgroups should be, and why.

We seek comment on all aspects of these potential approaches to varying the initial validation audit sample size and whether HHS should consider any other sampling approaches to determine sample sizes. We solicit comment on whether, beginning with 2019 benefit year risk adjustment data validation, we should vary sample size based on HCC failure rate outliers and issuers with lower and higher-than-average HCC failure rates' precision, incorporating minimum sample sizes for larger and smaller issuers with lower- or higher-than-average HCC failure rates, or varying sample size by issuer size only. Specifically, we seek comment on whether HHS should use the 2017 benefit year HCC failure rates to develop sample sizes for the 2019 benefit year, as HHS can only estimate an expected range in issuers' precisions to estimate the potential impact on sample size at this point in time. Finally, we request comment on whether HHS should maintain the current initial validation audit sampling approach of 200 enrollees for all issuers for 2019 benefit year risk adjustment data validation, while continuing to evaluate our sampling assumptions using actual enrollee data.

b. Second Validation Audit and Error Rate Discrepancy Reporting (§ 153.630(d)(2))

Under § 153.630(d)(2), issuers have 30 calendar days to confirm the findings of the second validation audit or the calculation of the risk score error rate, or file a discrepancy report, in the manner set forth by HHS, to dispute the foregoing. We propose to amend paragraph (d)(2) to shorten the window to confirm the findings of the second validation audit (if applicable) or the calculation of the risk score error rate, or file a discrepancy, to within 15 calendar days of the notification by HHS, beginning with the 2018 benefit

year risk adjustment data validation. We also clarify that there are two discrepancy reporting windows under § 153.630(d)(2). First, at the conclusion of the second validation audit, we will distribute to issuers their results for the given benefit year. These results would only include second validation audit findings in the event there is insufficient agreement between the initial validation audit and second validation audit results during the pairwise means analysis, and the second validation audit findings are used for the risk score error rate calculation. For issuers who receive second validation audit findings, the 15 calendar day window to confirm the findings or file a discrepancy, in the manner set forth by HHS, would begin when the second validation audit findings reports are issued. At the conclusion of the risk score error rate calculation process, we will distribute the risk score error rate calculation results to all issuers for the given benefit year. Once the risk score error rate calculation results are distributed, the 15 calendar day window to confirm the error rate calculation results or file a discrepancy, in the manner set forth by HHS, would begin. The proposed shorter discrepancy reporting timeframes are intended to ensure that we can resolve as many issues as possible in advance of publication of calculated risk adjustment transfer amounts under § 153.310(e), since any adjusted risk scores would result in an adjustment to risk adjustment transfers. Based on the first 2 pilot years of risk adjustment data validation, HHS believes that this shortened window would not be overly burdensome on issuers, and that any disadvantages of this shortened window would be outweighed by the benefits of timely resolution of as many discrepancies as possible prior to the release of the summary report on risk adjustment results by the end of June. We further note that a 15-day discrepancy reporting window is consistent with the initial validation audit sample and EDGE discrepancy reporting windows at §§ 153.630(d)(1) and 153.710(d), respectively.

We also propose to amend § 153.630(d)(2) to clarify the reference to the “audit and error rate” for which an issuer must confirm or file a discrepancy by replacing that phrase at the end of the provision with “the findings of the second validation audit (if applicable) or the calculation of a risk score error rate as a result of risk adjustment data validation.” We reiterate, as stated in the 2018 Payment Notice, that issuers are not permitted to

appeal the resolution of any interim discrepancy disputing the initial validation audit sample, or to file a discrepancy or appeal the results of the initial validation audit.⁵³ As detailed in the 2015 Payment Notice⁵⁴ and discussed later in this proposed rule, if sufficient pairwise means agreement is achieved, the initial validation audit findings will be used for purposes of the risk score error rate calculation, and therefore, those issuers will only be permitted to file a discrepancy or appeal the risk score error rate calculation. We seek comment on the proposed amendments to § 153.630(d)(2).

c. Default Data Validation Charge

Under § 153.630(b)(10), if an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or submit initial validation audit results, we impose a “default data validation charge,” which the regulation currently refers to in paragraph (b)(10) as a “default risk adjustment charge.” As explained in the 2015 Payment Notice, the default data validation charge is calculated in the same manner as the default risk adjustment charge under § 153.740(b).⁵⁵ With the 2017 benefit year being the first non-pilot year of risk adjustment data validation, and the first year for which HHS may impose the default data validation charge for noncompliance with applicable data validation requirements, we are proposing several amendments to clarify and further distinguish the default data validation charge assessed under § 153.630(b)(10) from the default risk adjustment charge assessed under § 153.740(b). First, we propose to amend § 153.630(b)(10) to replace the phrase “HHS will impose a default risk adjustment charge” with “HHS will impose a default data validation charge.” This change is intended to more clearly distinguish between the two separate risk adjustment-related default charges. Second, we propose to modify how the default data validation charge under § 153.630(b)(10) would be calculated. While we would generally continue to calculate the default data validation charge in the same manner as the risk adjustment default charge under § 153.740(b), we propose to calculate the default data validation charge based on the enrollment for the benefit year being audited in risk adjustment data validation, rather than the benefit year during which transfers would be adjusted as a result of risk adjustment

data validation. By way of example, if an issuer is subject to the default data validation charge for 2021 benefit year risk adjustment data validation and it offers risk adjustment covered plans in the same state risk pool in the 2022 benefit year, its default data validation charge would be calculated based on 2021 benefit year enrollment data (rather than 2022 benefit year enrollment data). Under this example, the default data validation charge this issuer would receive for failing to comply with the 2021 benefit year risk adjustment data validation requirements would equal a per member per month (PMPM) amount for the 2021 benefit year multiplied by the plan’s enrollment for the 2021 benefit year as follows:

$$T_n = C_n * E_n$$

Where:

T_n = total default data validation charge for a plan n ;
 C_n = the PMPM amount for plan n ;⁵⁶ and
 E_n = the total enrollment (total billable member months) for plan n .⁵⁷

Third, we propose to amend the allocation approach for distribution of default data validation charges among issuers. We propose to allocate a default data validation charge to the risk adjustment data validation issuers that were part of the same benefit year risk pool(s) as the noncompliant issuer. However, we would not allocate default data validation charges to any other noncompliant issuers in the same benefit year risk pool(s). This approach is consistent with the methodology for allocating the default risk adjustment charges under § 153.740(b), and includes all issuers in the same benefit year risk pool(s) that would be subject to a risk score adjustment as the result of other issuers’ risk adjustment data validation results. Issuers in the same benefit year risk pool(s) that are exempt from the risk adjustment data validation requirements would also be included in the allocation of any default data validation charges. Therefore, we propose to allocate any default data

⁵⁶ As established in the 2015 Payment Notice at 79 FR 13790, a PMPM default charge is equal to the product of the statewide average premium (expressed as a PMPM amount) for a risk pool and the 75th percentile plan risk transfer amount expressed as a percentage of the respective statewide average PMPM premiums for the risk pool. This rule does not propose any changes to this aspect of the calculation of the default data validation charge.

⁵⁷ In the 2015 Payment Notice at 79 FR 13790, we provided that E_n could be calculated using an enrollment count provided by the issuer, enrollment data from the issuer’s MLR and risk corridors filings for the applicable benefit year, or other reliable data sources. This rule does not propose any changes to the sources that could be used.

⁵³ 81 FR 94106.

⁵⁴ See 78 FR at 72334 through 72337 and 79 FR at 13761 through 13768.

⁵⁵ 79 FR at 13769.

validation charges collected from noncompliant issuers among the compliant and exempt issuers in the same benefit year risk pool(s) in proportion to their respective market shares and risk adjustment transfer amounts for the benefit year being audited for risk adjustment data validation.

As an illustrative example, there are 4 issuers (A, B, C, and D) in the individual non-catastrophic risk pool in state X for the 2017 benefit year, and an additional issuer, E, in the 2018 benefit year individual non-catastrophic risk pool in state X. For the 2017 benefit year:

- Issuer A does not comply with risk adjustment data validation and is assessed a default data validation charge.
- Issuer B was exempt from risk adjustment data validation for the 2017 benefit year because it was a small issuer (that is, it had 500 or fewer billable member months statewide in state X).
- Issuers C and D complied with applicable 2017 benefit year risk adjustment data validation requirements.
- Issuer E was not in the individual non-catastrophic risk pool in state X for 2017.

Issuer A's default data validation charge would be allocated to issuers B, C, and D in proportion to their 2017 transfer amounts and market shares. As detailed further below, this allocation would occur in the 2019 calendar year alongside the collection and payment of 2018 benefit year risk adjustment transfers. While Issuer B was not subject to risk adjustment data validation for the 2017 benefit year, it was still part of the same state market risk pool and would be subject to possible risk score adjustments due to the risk adjustment data validation results of issuers C and D. Since issuers C and D also participated in the individual non-catastrophic risk pool in state X for 2017 and complied with applicable data validation requirements, they would also receive part of Issuer A's default data validation charge. However, Issuer E was not part of the individual non-catastrophic risk pool in state X until 2018, and therefore would not receive any part of Issuer A's 2017 benefit year default data validation charge.

We intend to publish the default data validation charge information in the benefit year's report(s) released under § 153.310(e) in which transfers are adjusted based on risk adjustment data validation results, similar to how information on the risk adjustment default charge under § 153.740(b) is

currently provided.⁵⁸ Information on default data validation charges would be included as part of the summary risk adjustment report made publicly available beginning with the 2018 benefit year reports released under § 153.310(e). For example, for the 2017 benefit year risk adjustment data validation, we would publish information on default data validation charges and allocation of those charges to eligible 2017 benefit year issuers in the affected risk pools as part of the 2018 benefit year summary risk adjustment report. Following release of this report, these amounts would then be included as part of the monthly payment and collection processes described in 45 CFR 156.1215 alongside the collection of risk adjustment charges and payments calculated under the HHS-operated risk adjustment methodology.

Fourth, we clarify that a default data validation charge under § 153.630(b)(10) is separate from risk adjustment transfers for a given benefit year, unlike a default risk adjustment charge under § 153.740(b), which replaces the issuer's transfer amount for that benefit year. For example, if an issuer fails to submit initial validation audit results for the 2017 benefit year, it would receive a default data validation charge based on 2017 benefit year data calculated in accordance with the formula outlined above, if finalized as proposed. This default data validation charge for the 2017 benefit year would be in addition to, and separate from, the issuer's 2018 benefit year risk adjustment payment or charge amount as calculated under the HHS-operated risk adjustment methodology. This means that an issuer may owe both a default risk adjustment charge and a default data validation charge in the same calendar year (for example, in the 2019 calendar year, an issuer could owe a risk adjustment default charge for the 2018 benefit year and a default data validation charge for the 2017 benefit year risk adjustment data validation). Similarly, an issuer may owe in the same benefit year a risk adjustment charge for a given benefit year, alongside a default data validation charge for the benefit year being audited (for example, in the 2019 calendar year, an issuer could owe a risk adjustment charge for the 2018 benefit year as well as a default data validation charge for the 2017 benefit year).

⁵⁸ For example, see Section VII, Default Risk Adjustment Charge, in the *Summary Report on Permanent Risk Adjustment Transfers for the 2017 Benefit Year* (July 9, 2018), available at <https://downloads.cms.gov/cciio/Summary-Report-Risk-Adjustment-2017.pdf>.

We offer these proposals and clarifications about how HHS will assess and allocate the default data validation charge at this time to allow issuers to better understand the implications of noncompliance with initial validation audit requirements as risk adjustment data validation operations transition away from the pilot years of the program. The proposed amendments would apply beginning with the 2017 benefit year risk adjustment data validation.

We seek comment on these proposals.

d. Second Validation Audit Pairwise Means Test

In the 2014 Payment Notice, we provided that a second validation audit, will be conducted by an entity retained by HHS to verify the accuracy of the findings of the initial validation audit.⁵⁹ Consistent with § 153.630(c), HHS must select a subsample of the risk adjustment data validated by the initial validation audit for the second validation audit. In the 2015 Payment Notice, we indicated that to select the subsample, the second validation auditor will use a sampling methodology that allows for pairwise means testing to establish a statistical difference between the initial and second validation audit results.⁶⁰ This pairwise means test uses a 95 percent confidence interval (and a standard deviation of 1.96). To do pairwise means testing under the current approach, the second validation auditor tests a subsample of enrollees from an issuer's initial validation audit sample of 200 enrollees. If the pairwise means test results for a subsample indicate that the difference in enrollee results between the initial and second validation audits is not statistically significant, the initial validation audit results are used for calculation of HCC failure rates and risk score error rates. If the pairwise means test results for the subsample yields a statistically significant difference, the second validation auditor performs another validation audit on a larger subsample of enrollees from the initial validation audit. The results from the second validation audit of the larger subsample are again compared to the results of the initial validation audit using the pairwise means test with a subsample size of up to 100 enrollees. If there is no statistically significant difference between the initial and second validation audits of the larger subsample, HHS will apply the initial validation audit error results to

⁵⁹ 78 FR 15437.

⁶⁰ 79 FR 13761.

calculate the HCC failure rates and risk score error rates. However, if a statistically significant difference is found based on the second validation audit of the larger subsample up to 100 enrollees, HHS will apply the second validation audit results to the larger subsample to calculate the HCC failure rates and risk score error rates.

Based on the results of the second validation audit for the 2016 risk adjustment data validation pilot year, we propose to modify the statistical subsampling methodology to further expand the comparison of results between the initial and second validation audits beginning with the 2017 benefit year risk adjustment data validation. Specifically, when the larger subsample (of 100 enrollees) results indicate a statistically significant difference, we believe that further sampling by the second validation auditor is necessary and appropriate to determine whether the second validation audit results from the full sample should be used in place of the initial validation audit results. Therefore, we propose that, if a statistically significant difference is found based on the second validation audit of the larger subsample (of 100 enrollees), HHS would expand its sample to the full initial validation audit sample to consider whether the second validation audit results of the full sample or the subsample (of 100 enrollees) results should be used in place of initial validation audit results. Allowing the further testing of the sample provides assurance and confidence in the second validation audit results and the associated error estimation rate that would ultimately be used to adjust risk scores and transfers.

To determine whether to expand the second validation audit to the full initial validation audit sample, we propose to use a precision analysis. We would use precision metrics, including the standard error and confidence intervals, to determine if the second validation audit review of the larger subsample (of 100 enrollees) is of high or low precision. If the results of the second validation audit precision analysis determine that the precision level is good, HHS would use the second validation audit results for the larger subsample (of 100 enrollees) in place of the initial validation audit results for the error estimation and calculation of adjustments for plan average risk score, as applicable. However, if the second validation audit precision analysis for a larger subsample (of 100 enrollees) determines that the precision level is poor, the second validation audit would expand and use the full initial

validation audit sample of 200 enrollees for error estimation and calculation of adjustments for plan average risk score.

If any of the proposals to vary the initial validation audit sample size described above are finalized beginning with the 2019 benefit year risk adjustment data validation, we propose to maintain the maximum expansion of the sample for the pairwise comparison at 200 enrollees, and if the sample is smaller than 200 enrollees for an issuer's initial validation audit, the maximum expansion for pairwise means testing would be the full sample size.

We seek comments on these proposals.

e. Error Estimation for Prescription Drugs

Under § 153.350(c), we may adjust risk adjustment transfers to all issuers of risk adjustment covered plans in a state market risk pool based on adjustments to the average actuarial risk of a risk adjustment covered plan due to errors discovered during risk adjustment data validation. In the 2019 Payment Notice, we recognized that some variation and error should be expected in the compilation of data for risk scores, because providers' documentation of enrollee health status varies across provider types and groups.⁶¹ To avoid adjusting all issuers' risk scores, and by extension their risk adjustment transfers for expected variation and error, we finalized an approach in the 2019 Payment Notice that uses failure rates specific to HCC groups and subsequently adjusts each issuer's risk score when the issuer's failure rate for a group of HCCs is statistically different from the weighted mean failure rate for that group of HCCs for all issuers that submit initial validation audit results. We believe that determining outlier failure rates based on HCC groups yields a more equitable measure to evaluate statistically different HCC failure rates affecting an issuer's error rate than an approach based on an overall failure rate. Further, this approach is intended to streamline the risk adjustment data validation process and improve issuers' ability to predict risk score adjustments that would impact risk adjustment transfers (including adjustments made as a result of risk adjustment data validation results) while ensuring the integrity and quality of data provided by issuers.

Additionally, in the 2018 Payment Notice,⁶² we finalized that, starting with the 2018 benefit year, prescription drug utilization indicators would be

incorporated into the HHS risk adjustment models to create "hybrid" drug-diagnosis risk adjustment models for adults. To develop the hybrid drug-diagnosis risk adjustment models for adults, we finalized a set of clinically and empirically cohesive drug classes and created several Prescription Drug Categories (RXC) to select and to group drugs. Based on a set of principles to guide our decision-making,⁶³ we selected RXCs to impute diagnoses and to indicate the severity of diagnoses otherwise indicated through medical coding. Specifically, we created "payment" RXCs and interactions between RXCs and HCCs, referred to as "RXC-HCCs," that serve as indicators of incremental risk. The RXCs incorporated in the risk adjustment models for adults are closely associated to a specific HCC or group of HCCs that are potentially suitable for inclusion in the HHS risk adjustment models. When these RXCs are present, they can be used to impute a missing HCC, or to indicate the severity of a condition when coupled with a particular HCC. We also created "severity-only RXCs" that only indicate incremental risk when an HCC is also present for an enrollee. These severity-only RXCs are not included in the adult models to impute the associated diagnosis when an HCC is not present.⁶⁴ The incorporation of prescription drug data helps reduce incentives for issuers to avoid making available treatments for high-cost conditions in their formularies, and can effectively indicate health risk in cases where diagnoses may be missing. Because of the incorporation of payment RXCs into the risk adjustment models for adults beginning with the 2018 benefit year, we believe further modification may be appropriate to the error estimation methodology to take into account these RXCs' failure rates as part of the HHS risk adjustment data validation process.

HCCs are used in the 2017 risk adjustment data validation error estimation methodology finalized in the 2019 Payment Notice⁶⁵ in two key components of the methodology. First, the HCCs are grouped into low, medium, and high HCC groups based on the national failure rates for each HCC. Specifically, using data from the benefit year's risk adjustment data validation,

⁶³ These principles are outlined in the 2018 Payment Notice at 81 FR 94058 at 94075.

⁶⁴ The severity-only RXCs are included in the 2018 benefit year risk adjustment adult models, but are removed beginning with the 2019 benefit year risk adjustment models, as they did not meaningfully predict risk after being constrained. See 83 FR 16930 at 16941.

⁶⁵ 83 FR 16961–16967.

⁶¹ 83 FR 16961.

⁶² 81 FR 94058 at 94074–94080.

HHS first calculates the failure rate for each HCC in issuers' initial validation audit samples as:

$$FR^h = 1 - \frac{Freq_IVA^h}{Freq_EDGE^h}$$

Where:

$Freq_EDGE^h$ is the frequency of HCC code h occurring on EDGE, which is the number of sampled enrollees recording HCC code h on EDGE.

$Freq_IVA^h$ is the frequency of HCC code h occurring in initial validation audit results, which is the number of sampled enrollees with HCC code h in initial validation audit results.

FR^h is the failure rate of HCC code h .

h is the set of codes including all HCCs.⁶⁶

Based on the above calculation, HHS then creates three HCC groups (low, medium, and high) from the derived HCC failure rates. These HCC groups are determined by first ranking all HCC failure rates and then dividing the rankings into three groups, weighted by total observations or frequencies, of that HCC across all issuers' initial validation audit samples, to assign each unique HCC in the initial validation audit samples to a high, medium, or low failure rate group with an approximately even number of observations in each group. Those three HCC groupings are used to calculate each issuer's HCC group failure rate to set the national means and confidence intervals for each HCC group. These national confidence

intervals determine the thresholds for being an outlier for each of the three HCC groups, and the individual issuer's HCC group failure rates are compared to these national confidence intervals to determine if the issuer is an outlier.

Second, HCCs are used in the calculation of the issuer's error rate, which we use to adjust the issuer's risk score, if applicable. To calculate this adjustment, we first calculate the adjustment to an enrollee's total risk score, as the ratio of the total adjusted risk score for individual HCCs to the total risk score components for individual HCCs. Then, we calculate the total adjustment to an issuer's risk score amount across all HCCs per enrollee as:

$$Adjustment_{i,e} = \frac{\sum_{hcc} (RS_{i,e}^{hcc,G} * Adjustment_i^G)}{\sum_{hcc} (RS_{i,e}^{hcc,G})}$$

Where:

$RS_{i,e}^{hcc,G}$ is the risk score component of a single HCC code (belonging to HCC group G)

recorded on EDGE for Enrollee e of Issuer i .

$Adjustment_{i,e}$ is the calculated adjustment amount to adjust Enrollee e of Issuer i 's EDGE risk score.

In this rule, we propose to incorporate RXCs into the error estimation methodology beginning with the 2018 benefit year risk adjustment data validation error estimation, and are considering several alternatives for adding RXCs into these two parts of the risk adjustment data validation error estimation methodology, as outlined further below. We seek comments on all of the proposals and alternatives, including an alternative method described later in this section that would not require changes to the error estimation methodology to incorporate RXCs into HHS risk adjustment data validation.

In considering how to incorporate prescription drugs in the error estimation methodology, we recognize that differences between HCCs and RXCs need to be considered. Specifically, RXCs and HCCs are interdependent in the enrollee's risk score

calculation and the risk score impact of RXCs can reflect interaction terms of the RXC between more than one HCC.

Additionally, the method for validating an enrollee's RXC would be different than the method for validating an enrollee's HCC. Specifically, our assumption is that it may be more straightforward for initial validation auditors to validate an RXC than an HCC because in many cases, only a validated prescription would need to be obtained to validate the RXC, whereas HCC validation requires recoding a medical record, which likely has the potential for greater variation.

With these considerations in mind, the first proposal we are considering would incorporate RXCs into the HCC failure rate methodology by adding each RXC as a separate factor, similar to an "HCC", for classification into the low, medium, and high HCC groups determined by the national failure rates for each RXC. For example, because there are 12 RXCs and 128 single component HCCs in the 2018 benefit

year,⁶⁷ incorporating RXCs in this manner would mean that the number of factors for groupings for risk adjustment data validation would increase from 128 HCCs to 140 HCCs/RXCs. To apply this change to the error estimation methodology finalized in the 2019 Payment Notice, we propose the definition of superscript h would expand to a list of codes including both the 128 HCCs and 12 RXCs whereby HHS would first calculate the failure rate for each HCC and RXC in issuers' samples as:

$$FR^{h_r} = 1 - \frac{Freq_IVA^{h_r}}{Freq_EDGE^{h_r}}$$

Where:

h_r is the set of codes including 128 HHS HCCs and 12 RXCs.

$Freq_EDGE^{h_r}$ is the frequency of HCC code h or RXC code r occurring on EDGE, which is the number of sampled enrollees recording HCC code h or RXC code r on EDGE.

⁶⁶To clarify the formula finalized in the 2019 Payment Notice, we added the definition of h , which was included in the 2019 Payment Notice, but was not explicitly defined.

⁶⁷The proposed RXC methodologies in this section are intended to start applying with the 2018

benefit year risk adjustment data validation where there was 12 RXCs being used in the risk adjustment models for adults; however, starting with the 2019 benefit year, the two severity-only RXCs are removed from the adult risk adjustment models. See 83 FR at 16941. Therefore, only 10

RXCs exist for the 2019 benefit year and adoption of this proposal would mean that the number of factors for groupings for risk adjustment data validation would increase for 2019 benefit year risk adjustment data validation from 128 HCCs to 138 HCCs/RXCs.

$Freq_IVA^h_r$ is the frequency of HCC code h or RXC code r occurring in initial validation audit results, which is the number of sampled enrollees with HCC code h or RXC code r in initial validation audit results.

FR^h_r is the failure rate of HCC code h or RXC code r .

HHS would then create three “HCC/RXC” groups based on the HCC failure rates and RXC failure rates derived in the calculation above. These “HCC/RXC” failure rate groups would rank all HCC failure rates and RXC failure rates to assign each unique HCC and RXC in the initial validation audit samples to a high, medium, or low failure rate group. To assign each HCC and RXC to a “HCC/RXC” failure rate group, we propose to use the current HCC failure rate ranking methodology that ranks each HCC/RXC failure rate divided into three groupings based on weighted total observations or frequencies of that HCC/RXC across all issuers’ initial validation sample, or assigning HCCs and RXCs failure rates by taking into consideration the ranking of related HCCs and RXCs in the grouping. Under this proposed approach, we would maintain a single classification for HCC and RXC high, medium, or low groups, instead of creating two separate classifications of RXCs and single component HCCs. We believe this proposed approach would be the most simplified manner to incorporate RXCs and builds upon the current HCC group failure rate methodology.

Alternatively, we could incorporate the RXCs as a separate “HCC” grouping in the error estimation methodology. Under this proposed approach, we would keep the 128 HCCs in the three groups, but combine all RXCs into an

additional, fourth separate group. Therefore, a separate RXC and the HCCs groups would be created, and their failure rates would be computed within those four groupings. This proposed approach to group RXCs would be the same as for HCC groupings, which is based on the failure rates FR^r of the 12 RXCs:

$$FR^r = 1 - \frac{Freq_IVA^r}{Freq_EDGE^r}$$

Where:

r is the set of 12 RXCs.

$Freq_EDGE^r$ is the frequency of RXC code r occurring on EDGE, which is the number of sampled enrollees recording RXC code r on EDGE.

$Freq_IVA^r$ is the frequency of RXC code r occurring in initial validation audit results, which is the number of sampled enrollees with RXC code r in initial validation audit results.

FR^r is the failure rate of RXC code r .

While we assume that RXCs may be easier to validate, this type of approach could take into consideration the potential differing failure rates within the RXC groupings as opposed to the single component HCC groupings, or isolate the RXC failure rates to a separate grouping from HCCs before applying those failure rates to the error rate calculation. This alternative approach would also result in an additional grouping in the error estimation methodology, and having more groupings means that the number of groupings where it is possible for an issuer to be an outlier would increase. Further, in the event that all RXCs do not have similar, low failure rates, the confidence interval for an RXC-only group could be quite large, resulting in a significant difference between the

outliers’ failure rates to the group’s failure rate mean, and by extension, could result in a larger failure rate adjustment factor for the RXC-only group.

In addition to adopting one of the above approaches to group RXCs as part of the error estimation methodology, we would also need to incorporate RXCs into the error rate calculation under the error estimation methodology. To do so, we propose three alternative approaches to incorporate and adjust for RXCs and RXC–HCC interaction factors in the error rate calculation. The error rate calculation represents the issuer’s risk score error rate as a result of risk adjustment data validation and constitutes the percentage of the issuer’s risk score that is incorrect due to the issuer’s outlier group failure rate(s). As an example, an issuer could have a 50 percent failure rate for a group of HCCs, in that twenty of forty instances of the HCC could not be validated. The impact of that HCC failure rate on an issuer’s error rate calculation will then depend on the mean group failure rate where the issuer was identified as an outlier, the magnitude of the HCCs’ coefficients in that group, and the incidence of those HCCs in the audit sample.

One option to incorporate the RXCs in the error rate calculation that we propose would be to add RXCs to the current methodology of calculating error rates, without accounting for any HCC–RXC interaction factors. To incorporate RXCs in the current error rate calculation, we propose to modify the formula to calculate an enrollee’s adjustment $Adjustment_{i,e}$ as follows:

⁶⁸ 83 FR 16930 at 16963.

$$Adjustment_{i,e} = \frac{\sum_c (RS_{i,e}^{c,G} * Adjustment_i^G)}{\sum_c (RS_{i,e}^{c,G})}$$

Where:

$RS_{i,e}^{c,G}$ is the risk score component of a single HCC or RXC code c (belonging to HCC/RXC group G) recorded on EDGE for Enrollee e of Issuer i .

This proposed approach would be the simplest approach to adjusting RXCs in the error rate calculation, as $RS_{i,e}^{c,G}$ generally remains the same definition as in the 2019 Payment Notice⁶⁸ for $RS_{i,e}^{hcc,G}$ and the resulting calculation would be completed as follows:

$$RS_{i,e}^{c,G} = RS_{i,e}^{c_hcc/rxc,G}$$

Where:

$RS_{i,e}^{c_hcc/rxc,G}$ is the risk score component of a code c as a single HCC or RXC, without considering the interaction coefficients between code c and other codes for Enrollee e of Issuer i .

However, this proposed approach would mean that the interaction of the risk score coefficients between the

single component HCC and the RXC are not considered in the error rate

calculation, which may be an oversimplification of this calculation.

Alternatively, we solicit comments on the adjustment of the RXCs in the error rate calculation as part of the risk score coefficient for a single component HCC by adjusting the risk score coefficient of the RXC-HCC interaction factor, if the coefficient exists. This step would start with the coefficient for a single component HCC and RXC and then adjust both single component coefficients with the full interaction term for both the HCC and RXC to calculate the error rate. Under this proposed approach, if there is no coefficient, the single component HCC and RXC would not be adjusted by an interaction term. Under this proposed approach, $RS_{i,e}^{c,G}$ would be defined as:

$$RS_{i,e}^{c,G} = RS_{i,e}^{c_hcc/rxc,G} + RS_{i,e}^{c_x_hXr,G}$$

Where:

$RS_{i,e}^{c_hcc/rxc,G}$ is the risk score component of a code c as a single HCC or RXC, without considering the interaction coefficients between code c and other codes for Enrollee e of Issuer i .

$RS_{i,e}^{c_x_hXr,G}$ is the risk coefficient for the interaction between an HCC and an RXC, with the interaction term existing between code c and another code x for Enrollee e of Issuer i .

G is the HCC/RXC group for code c .

For example, if an Enrollee (e) of Issuer (i) coded HCC 48 (Inflammatory Bowel Disease) and RXC 05 (Inflammatory Bowel Disease Agents) on EDGE, the risk component for HCC 48 ($RS_{i,e}^{hcc48,G}$) is calculated as:

$$RS_{i,e}^{hcc48,G} = RS_{i,e}^{hcc48_hcc/rxc,G} + RS_{i,e}^{hcc48_rxc05_hXr,G}$$

The risk component for RXC 05 ($RS_{i,e}^{rxc05,G}$) is calculated as:

$$RS_{i,e}^{rxc05,G} = RS_{i,e}^{rxc05_hcc/rxc,G} + RS_{i,e}^{rxc05_hcc48_hXr,G}$$

Both $RS_{i,e}^{hcc48_rxc05_hXr,G}$ and $RS_{i,e}^{rxc05_hcc48_hXr,G}$ would be calculated using the

interaction term.

In short, this alternative proposed approach for incorporating RXCs in the error rate calculation would capture the sampled enrollee's characteristics and interaction between the single component HCC and RXC that may provide a more accurate calculation than not accounting for any interaction between the single component HCC and RXC. However, this proposed approach would add an additional step to the error rate calculation, whereby the risk score coefficient for a condition would be adjusted by the interaction coefficients between the single component HCC and the RXC and would take into account the full interaction coefficient separately for the HCC and RXC, which may result in an over-adjustment for the interaction terms.

A third alternative to incorporating RXCs as part of the error rate calculation would be to adjust the risk score coefficient for a single component HCC and RXC by a modified interaction coefficient between the single component HCC and RXC indicator, if the coefficient exists. If there is no coefficient, the single component HCC and the RXC would not be adjusted by an interaction coefficient. This alternative approach would capture a sampled enrollee's specific characteristics and interaction between HCC and RXC and modify the interaction such that the total adjustments are equal to the total interaction term value. That is, if an interaction would be applied to two codes, each of the codes receives a fraction of the interaction adjustment that equals the full value of the interaction factor. Specifically, this approach would add two steps to the risk score error rate calculation, first, to include interaction terms and second, to modify the interaction to ensure that it does not exceed the interaction term, which would be more complex to implement. However, this proposed approach would have the benefit of limiting the potential for over- or under-adjusting an issuer's risk score error rate to account for interaction terms because the total adjustment would not exceed the interaction term. Thus, this alternative could provide a balanced approach between the two previous proposed options for incorporating RXCs as part of the error rate calculation where no HCC and RXC interactions were being considered or the impact of HCC and RXC interaction terms was not being limited.

We also generally solicit comment on how to weight risk score coefficients and account for the interaction terms between the single component HCC and

the RXCs in calculating the error rate under these alternative proposed approaches. Additionally, in the error estimation methodology finalized in the 2019 Payment Notice, we did not include the severity illness indicator interactions for HCCs as they can be triggered by multiple combinations of HCCs, which would be overly complex to implement. As part of our current evaluation of the impact of adjusting for the RXC-HCC interactions in the error estimation methodology, we also seek comment on whether we should similarly not adjust for the RXC-HCC interactions.

We solicit comment on all of these proposed approaches for incorporating RXCs into the error estimation methodology and error rate calculation, including whether we should consider alternative options. For example, for the 2018 benefit year, we could finalize one method for incorporating RXCs into the error estimation process with the intention of reconsidering that method for future benefit years once we have data and experience from the 2018 benefit year risk adjustment data validation.

As an alternative to the aforementioned proposed policies, we are also considering other methods for incorporating RXCs (or all drugs) into the risk adjustment data validation process rather than as part of the error estimation methodology and error rate calculation. Since it may be significantly easier to validate RXCs than HCCs, we could treat RXC errors as a data submission issue. Specifically, we could incorporate RXCs or all drugs into risk adjustment data validation as a method of discovering materially incorrect EDGE server data submissions in the same or similar manner to how we address demographic and enrollment errors discovered during risk adjustment data validation.⁶⁹ Under this alternative proposed approach, instead of incorporating RXCs into the error estimation methodology and error rate calculation, we would treat RXC or general drug errors discovered during risk adjustment data validation in a manner similar to an EDGE data discrepancy, which is addressed in the current benefit year under § 153.710(d). As such, these RXC or general drug errors would be the basis for an adjustment to the applicable benefit year risk score and original transfer amount, rather than the subsequent benefit year risk score. Any material errors identified through this process would result in a decrease to the issuer's original risk score, thereby resulting in

a reduced risk adjustment payment or an increased risk adjustment charge for that issuer. If this alternative approach is adopted, the identification of RXC or general drug errors could also have the effect of reducing charges or increasing payments to other issuers in the state market risk pool, holding constant the other elements of the state payment transfer formula. We solicit comment on this alternative approach, especially in comparison to the proposals for incorporating RXCs into the error estimation methodology and/or error rate calculation, and on whether other specific requirements would be needed to verify materiality of risk score impacts if we were to treat RXC or general drug errors discovered during risk adjustment data validation as a data submission issue through the EDGE data discrepancy process under § 153.710(d).

f. Risk Adjustment Data Validation Adjustments in Exiting and Single Issuer Markets and Negative Error Rate Outlier Markets

Under the risk adjustment data validation program, adjustments to transfers are generally made in the benefit year following the benefit year that was audited. For issuers that exit the market following the benefit year being audited, and therefore do not have transfers to adjust during the following benefit year, we have previously finalized an exception to this general rule such that we will adjust the exiting issuer's prior year risk scores and associated transfers where it has been identified as an outlier through the HCC failure rate methodology during risk adjustment data validation.⁷⁰ We propose to amend our policy to provide that, if an exiting issuer is found to be a negative error rate outlier, HHS will not make adjustments to that issuer's risk score and its associated risk adjustment transfers as a result of this negative error rate outlier finding. A negative error rate would have the effect of increasing an issuer's risk score and thereby increasing their calculated risk adjustment payment or reducing their calculated risk adjustment charge. To avoid retroactively re-opening a risk pool to make adjustments to other issuers' transfers based on an exiting issuer's negative error rate, we propose to re-open the issuer's risk score and its associated risk adjustment transfers in a prior benefit year only if the exiting issuer was found to have had a positive error rate, and was therefore, overpaid or undercharged based on its risk adjustment data validation results. When the exiting issuer is a positive

⁶⁹ See 83 FR 16930 at 16970 through 16971.

⁷⁰ 83 FR at 16965.

error rate outlier, HHS would collect funds (either increasing the charge amount or reducing the payment amount) from the exiting issuer and redistribute the amounts to other issuers who participated in the same state market risk pool in the prior benefit year. This proposed approach is intended to help ensure that issuers are made whole even if an issuer with a positive error rate exits the state, without the additional burdens associated with having transfers adjusted (including the potential for additional charges being assessed) for a prior benefit year for a negative error rate outlier when an issuer decides to exit a state.

Further, we also propose that to be considered an exiting issuer under this proposed policy, that issuer would have to exit all of the markets and all of the risk pools in the state (that is, not selling or offering any new plans in the state). If an issuer only exits some of the markets or risk pools in the state, but continues to sell or offer new plans in others, it would not be considered an exiting issuer under this proposed policy. Finally, we clarify that under this proposal, small group market issuers with off-calendar year coverage who exit the market but only have carry-over coverage that ends in the next benefit year (that is, carry-over of run out claims for individuals enrolled in the previous benefit year, with no new coverage being offered or sold) would be considered an exiting issuer and would be exempt from risk adjustment data validation for the benefit year with the carry-over coverage. Individual market issuers offering or selling any new individual market coverage in the subsequent benefit year would be subject to risk adjustment data validation, unless another exemption applies. These proposed policies, if finalized, would be effective for 2017 benefit year risk adjustment data validation and beyond. We solicit comment on these proposals and on the potential impact of any carry-over coverage by individual market plans and how HHS would be able to confirm that any individual market plan has carry-over coverage.

We also propose to clarify how we would approach applying risk adjustment data validation results in circumstances where an issuer is entering what was previously a sole issuer risk pool. For issuers that are the sole issuer in a state market risk pool in a benefit year, there are no risk adjustment transfers under the state payment transfer formula and thus, no payment or financial accountability to

other issuers for that risk pool.⁷¹ We do not calculate risk adjustment transfers for a benefit year in a state market risk pool in which there is only one issuer, and that issuer is not required to conduct risk adjustment data validation for that state market risk pool.⁷² However, if the sole issuer was participating in multiple risk pools in the state during the year that is being audited, that issuer would be subject to risk adjustment data validation for those risk pools with other issuers that had risk adjustment transfers calculated. In addition, the sole issuer may have been identified as an outlier for risk adjustment data validation, and its error rate would be applied to all of the issuer's risk adjustment covered plans in the state's market risk pools where it was not the sole issuer. Its error rate would also be applied to adjust the subsequent benefit year's transfers for other issuers in the same state market risk pool(s). If that sole issuer participated in risk adjustment data validation for the benefit year, and in the following benefit year, a new issuer entered the formerly sole issuer risk pool, we propose that the formerly sole issuer's error rate would also apply to the risk scores for its risk adjustment covered plans in the subsequent benefit year in the risk pool(s) in which it was formerly the sole issuer—that is, the formerly sole issuer's risk scores and transfer amounts calculated for the benefit year in which a new issuer entered the state market risk pool which did not have risk adjustment transfers calculated in the prior year would be subject to adjustment based on the formerly sole issuer's error rate. In addition, the new issuer may also have its risk adjustment transfer adjusted in the subsequent benefit year if the formerly sole issuer was an outlier with risk score error rates in the prior benefit year's risk adjustment data validation. This is consistent with the policy established in the 2015 Payment Notice, specifying that each issuer's risk score adjustment (from risk adjustment data validation results) will be applied to adjust the plan's average risk score for each of the issuer's risk adjustment covered plans.⁷³ This proposed policy also aligns with how error rates would be applied if a new issuer entered a state market risk pool with more than one issuer. This proposed policy, if finalized, would be effective for 2017 benefit year risk adjustment data

validation and beyond. We solicit comment on this proposal.

Lastly, as discussed in this section earlier, if an issuer is a negative error rate outlier, its risk score would be adjusted upwards. Assuming no changes to risk scores for the other issuers in the risk pool, this upward adjustment would reduce the issuer's risk adjustment charge or increase its risk adjustment payment for the applicable benefit year, leading to an increase in risk adjustment charges or a decrease in risk adjustment payments for the other non-outlier issuers in the state market risk pool. The intent of this two-sided outlier identification, and the resulting adjustments for outlier issuers that have significantly better than average (negative error rate) and poorer than average (positive error rate) data validation results is to ensure that risk adjustment data validation adjusts risk adjustment transfers for identified, material risk differences between what issuers submitted to their EDGE servers and what was validated in medical records. The increase to risk score(s) for negative error rate outliers is consistent with the upward and downward risk score adjustments that were finalized as part of the original risk adjustment data validation methodology in the 2015 Payment Notice⁷⁴ and the HCC failure rate approach to error estimation finalized in the 2019 Payment Notice. That is, the long-standing intent of HHS-operated risk adjustment data validation has been to account for identified risk differences, regardless of the direction of those differences. Except as proposed above for negative error rate outliers from exiting issuers, we believe that adjusting for both negative and positive error rate outliers ensures that issuers' actuarial risk is reflected in transfers and incentivizes issuers to achieve the most accurate EDGE data submissions for initial risk adjustment transfer calculations; therefore, we do not believe that further changes are needed to the error estimation methodology or the outlier adjustment policy to account for the impact of negative error rate outliers on non-outlier issuers in the state market risk pool at this time.

The 2016 benefit year risk adjustment data validation pilot year results suggested that there could be a large number of negative error rate outlier issuers affecting numerous state market risk pools, but this result was largely due to the modifications made to the

⁷¹ See 83 FR at 16967.

⁷² Id.

⁷³ 79 FR 13743 at 13768–13769.

⁷⁴ For example, we stated in the 2015 Payment Notice that “the effect of an issuer's risk score error adjustment will depend upon its magnitude and direction compared to the average risk score error adjustment and direction for the entire market”. See 79 FR 13743 at 13769.

2016 benefit year national benchmarks, which dropped a large number of high HCC failure rate outliers from the calculations, artificially increasing the number of negative error rate outliers. We do not yet have 2017 risk adjustment data validation results and therefore do not know whether the number of negative error rate outlier issuers and the size of the negative error rates would be significant in a risk adjustment data validation year that results in risk score adjustments. Therefore, we are seeking comment on the impact of the current approach under the error estimation methodology and the outlier adjustment policy for negative error rate outlier issuers, or issuers with significantly lower-than-average HCC failure rates, on other issuers in a state market risk pool, the incentives that negative error rate adjustments may create, and potential modifications to the error rate estimation methodology or the outlier adjustment policy, such as to utilize the state mean failure rate instead of the national mean failure rate, to modify the error rate calculation to the confidence interval instead of the mean, to exclude negative error rate outliers or to use other methods of lessening the impact of negative error rate issuers on affected risk pools, beginning with the 2018 benefit year of risk adjustment data validation or later.

g. Exemptions From Risk Adjustment Data Validation

In previous rules,⁷⁵ we established exemptions from the HHS-operated risk adjustment data validation requirements for issuers with 500 or fewer billable member months statewide and issuers at or below a materiality threshold for the benefit year being audited. Additionally, on April 9, 2018, we released guidance indicating that we intended to propose a similar exemption from risk adjustment data validation requirements for certain issuers in or entering liquidation.⁷⁶ The purpose of these policies is to address numerous concerns, particularly from smaller issuers, regarding the regulatory burden and costs associated with complying with the HHS-operated risk adjustment data validation program. HHS has previously considered these concerns and provided relief where possible, and under this proposed rule, we propose to

codify these exceptions in regulation at § 153.630(g), as described below.

In the 2019 Payment Notice, we finalized that beginning with 2017 benefit year HHS-operated risk adjustment data validation, issuers with 500 billable member months or fewer statewide in the benefit year being audited that elect to establish and submit data to an EDGE server will not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results.⁷⁷ We explained that exempting these issuers from the requirement to hire an initial validation auditor is appropriate because they would have a disproportionately high operational burden for compliance with risk adjustment data validation. We noted that, beginning with 2018 benefit year risk adjustment data validation, these issuers would not be subject to random (and targeted) sampling under the materiality threshold discussed below, and they would continue to not be subject to the requirement to hire an initial validation auditor or submit initial validation audit results. Issuers who qualify for this exemption would not be subject to enforcement action for non-compliance with risk adjustment data validation requirements, or be assessed the default data validation charge under § 153.630(b)(10). We stated that the determination of whether an issuer has 500 or fewer billable member months would be made on a statewide basis (that is, by combining an issuer's enrollment in a state's individual, small group, and merged markets, as applicable, in a benefit year). In this proposed rule, we propose to codify this exemption at § 153.630(g)(1) beginning with the 2017 benefit year of risk adjustment data validation.

Second, in the 2018 Payment Notice, HHS finalized a materiality threshold for risk adjustment data validation to ease the burden of annual audit requirements for smaller issuers of risk adjustment covered plans.⁷⁸ We evaluated the burden associated with risk adjustment data validation, particularly, the fixed costs associated with hiring an initial validation auditor and submitting results to HHS. We established a materiality threshold for risk adjustment data validation that considered the burden of such a process on smaller plans. Specifically, we stated that issuers with total annual premiums at or below \$15 million for risk adjustment covered plans (calculated statewide based on the premiums of the benefit year being validated) will not be

subject to the annual initial validation audit requirements, but will still be subject to an initial validation audit approximately every 3 years (barring any risk-based triggers due to experience that would warrant more frequent audits). Under the established process, we will conduct random and targeted sampling for issuers at or below the materiality threshold, beginning with the 2018 benefit year of risk adjustment data validation. We noted that, even if an issuer is exempt from initial validation audit requirements under the materiality threshold, HHS may require these issuers to make records available for review or to comply with an audit by the federal government under § 153.620.

In this rule, we propose to codify the materiality threshold policy at § 153.630(g)(2), providing that an issuer of a risk adjustment covered plan will be exempt from the data validation requirements in § 153.630(b) if the issuer is at or below the materiality threshold defined by HHS and is not selected by HHS to participate in the data validation requirements in an applicable benefit year under a random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers due to experience that would warrant more frequent participation in risk adjustment data validation), beginning with the 2018 benefit year of risk adjustment data validation.⁷⁹

Consistent with the materiality threshold finalized in the 2019 Payment Notice,⁸⁰ we propose to define the materiality threshold as total annual premiums at or below \$15 million, based on the premiums of the benefit year being validated for all of the issuer's risk adjustment covered plans in the individual, small group, and merged markets (as applicable) in the state. We solicit comments on the definition of materiality and whether the materiality threshold should be adjusted in future benefit years, given the potential for increased premiums and decreased enrollment in certain state market risk pools. We are not proposing such an adjustment to the materiality threshold at this time, but if we were to modify the definition of materiality to trend the \$15 million threshold in future benefit years, we

⁷⁵ See 81 FR 94058 at 94104 and 83 FR 16930 at 16966.

⁷⁶ Exemption from HHS-Operated Risk Adjustment Data Validation (HHS-RADV) for Issuers in Liquidation or Entering Liquidation (April 9, 2018). <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/RADV-Exemption-for-Liquidation-Guidance.pdf>.

⁷⁷ 83 FR 16930 at 16966.

⁷⁸ 81 FR 94058 at 94104–94105.

⁷⁹ When selecting issuers at or below the materiality threshold for more frequent initial validation audits, we would consider the issuer's prior risk adjustment data validation results and any material changes in risk adjustment data submissions, as measured by our quality metrics. See 81 FR 94105.

⁸⁰ See 83 FR 16966.

would propose that change through notice and comment rulemaking.

We note that if an issuer of a risk adjustment covered plan within the materiality threshold is not exempt from the data validation requirements for a given benefit year (that is, the issuer is selected for a random and targeted sampling), and fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, the issuer would be subject to a default data validation charge in accordance with § 153.630(b)(10) and may be subject to other enforcement action.

Lastly, as noted above, HHS released guidance on April 9, 2018 indicating our intention to propose in future rulemaking an exemption from risk adjustment data validation requirements for certain issuers in liquidation or that will enter liquidation. The purpose of exempting these issuers is similar to the reasons outlined above for smaller issuers and those below the materiality threshold—to recognize the burdens and costs associated with the risk adjustment data validation requirements on these issuers given their reduced financial and staff resources. Under this proposal, certain issuers in liquidation or that will enter liquidation would be exempt from the requirement to hire an initial validation auditor and submit initial validation audit results, as well as the second validation audit requirements, and would not be subject to enforcement actions for non-compliance with risk adjustment data validation requirements or be assessed the default data validation charge under § 153.630(b)(10).

In this proposed rule, we propose to codify at § 153.630(g)(3) that an issuer would be exempt from the applicable benefit year of risk adjustment data validation if the issuer is in liquidation as of April 30th of the year when transfer adjustments based on data validation results are made (that is, 2 benefit years after the benefit year being audited). We propose to apply this exemption starting with the 2017 benefit year risk adjustment data validation. For example, a 2017 benefit year risk adjustment data validation issuer would need to be in liquidation on or before April 30, 2019 to be eligible for the proposed exemption. For the 2018 benefit year and beyond, we propose that to qualify for the exemption, the issuer must also not be a positive error rate outlier in the prior benefit year of risk adjustment data validation (that is, the issuer is not a positive error rate outlier under the error estimation methodology in the prior year's risk adjustment data validation) as outlined

in proposed paragraph (g)(3)(ii). If an issuer in liquidation or that would enter liquidation by the applicable date was a positive error rate outlier in the previous year's risk adjustment data validation, we propose not to exempt the issuer from the subsequent benefit year's risk adjustment data validation, and the issuer would be required to participate in risk adjustment data validation or receive the default data validation charge in accordance with § 153.630(b)(10) unless another exemption applies.

To qualify for this exemption in any year, we propose under paragraph (g)(3)(i) that the issuer must provide to HHS, in a manner and timeframe to be specified by HHS, an attestation that the issuer is in or will enter liquidation no later than April 30th 2 years after the benefit year being audited that is signed by an individual with the authority to legally and financially bind the issuer. In paragraph (g)(3)(iii), we propose to define liquidation as meaning that a state court has issued an order of liquidation for the issuer that fixes the rights and liabilities of the issuer and its creditors, policyholders, shareholders, members, and all other persons of interest.

Our intention with this proposed policy is to align the definition of liquidation with state law on liquidation of health insurance issuers and the National Association of Insurance Commissioners' Model Act on receivership where possible.⁸¹ Thus, we solicit general comments on this proposed definition, and on whether modifications are needed to this definition to better align with state law. Additionally, we specifically solicit comments on the proposed April 30th date by which the issuer must be in liquidation and the advantages and disadvantages of potentially using a later date as the deadline by which the issuer must be in liquidation to be eligible for this proposed exemption. We also seek comment on whether the proposed April 30th date by which the issuer must be in liquidation should be later for the 2017 benefit year only.

While we understand that the exact date of a liquidation order may be uncertain in specific circumstances, we propose that the individual signing the attestation must be reasonably certain that the issuer would enter liquidation by April 30th 2 benefit years after the benefit year being audited.

Under our proposal, we would accept an attestation from a representative of

the state's department of insurance, an appointed liquidator, or other appropriate individual who can legally and financially bind the issuer. HHS would verify the issuers' liquidation status with the applicable state regulators for issuers who submitted an attestation under § 153.630(g)(3). We also propose that, because the April 30th two benefit years after the benefit year being audited is after the deadline for completing the initial validation audit for a given benefit year, an issuer who submits an attestation for this exemption but is determined by HHS to not meet the criteria for the exemption would receive a default data validation charge in accordance with § 153.630(b)(10) if the issuer fails to complete or comply with the risk adjustment data validation process within the established timeframes for the given benefit year, unless another exemption applies.

Additionally, we also note that any issuer that qualifies for any of the three exemptions in proposed § 153.630(g) would not have its risk score and its associated risk adjustment transfers adjusted due to its own risk score error rate, but that issuer's risk score and its associated risk adjustment transfers could be adjusted if other issuers in that state market risk pool were outliers and received risk score error rates for that benefit year's risk adjustment data validation. We solicit comments on the proposed codification of the exemptions for issuers with 500 or fewer billable member months statewide and issuers at or below a materiality threshold, as well as the new proposed exemption for certain issuers who are in, or would be entering liquidation.

We solicit comments on these proposals.

E. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Definitions (§ 155.20)

We propose to amend § 155.20 to add definitions of “direct enrollment technology provider,” “direct enrollment entity,” “direct enrollment entity application assister,” and “web-broker”. For a discussion of these proposed changes, please see the preamble to §§ 155.220, 155.221, and 155.415.

We seek comment on these proposals.

2. General Functions of an Exchange

a. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

Section 1311(d)(4)(B) of the PPACA requires an Exchange to provide for the operation of a toll-free telephone hotline

⁸¹ National Association of Insurance Commissioners Model Act, Issuer Receivership Act. 2007. <http://www.naic.org/store/free/MDL-555.pdf>.

to respond to requests for assistance. In the 2017 Payment Notice, we explained the distinction between a toll-free call center and a toll-free hotline, for purposes of specifying the different requirements for SBE-FPs and other Exchanges.⁸² In the 2019 Payment Notice, we finalized regulations providing for a leaner FF-SHOP implementation, and have adopted that approach. In that rulemaking, we explained that the FF-SHOPs would continue to provide call centers to answer questions related to the SHOP.⁸³ Currently, employers purchase and enroll their employees in new FF-SHOP coverage through issuers and through agents and brokers registered with the FFE, and no longer enroll in SHOP coverage using an online FF-SHOP platform.

Under this approach, FF-SHOP call center volume has been extremely low. Given this experience, we propose to amend § 155.205(a) to allow SHOPs operating in the leaner fashion described in the 2019 Payment Notice to operate a toll-free telephone hotline, as required by section 1311(d)(4)(B) of the PPACA, and to eliminate the requirement to operate a more robust call center. We propose to amend the interpretation provided in the 2017 Payment Notice of what is required to establish a toll-free hotline, as required by section 1311(d)(4)(B) of the PPACA. There, we stated that a toll-free hotline includes the capability to provide information to consumers and appropriately direct consumers to the federally operated call center or *HealthCare.gov* to apply for, and enroll in, coverage through the Exchange. Given that SHOPs that operate in the leaner fashion no longer offer online enrollment and to reflect the option for such SHOPs to provide a toll-free hotline, rather than a more robust call center, we propose that a toll-free hotline include the capability to provide information to consumers about eligibility and enrollment processes, and to appropriately direct consumers to the applicable Exchange website and other applicable resources.

The toll-free hotline provided by such SHOPs would consist of a toll-free number linked to interactive voice response capability, with prompts to pre-recorded responses to frequently asked questions, information about locating an agent and broker in the caller's area, and the ability for the caller to leave a message regarding any additional information needed. We believe this hotline would adequately

address the needs of potential FF-SHOP consumers requesting assistance, and appropriately direct consumers to services to apply for, and enroll in, FF-SHOP coverage.

b. Navigator Program Standards (§ 155.210)

Section 1311(d)(4)(K) and 1311(i) of the PPACA require each Exchange to establish a Navigator program under which it awards grants to entities to conduct public education activities to raise awareness of the availability of QHPs, distribute fair and impartial information concerning enrollment in QHPs, the availability of premium tax credits, and cost-sharing reductions; facilitate enrollment in QHPs; provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate state agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange. The statute also requires the Secretary to develop standards to ensure that information made available by Navigators is fair, accurate, and impartial. We have implemented the statutorily required Navigator duties through regulations at § 155.210 (for all Exchanges) and § 155.215 (for Navigators in FFEs).

Further, section 1311(i)(4) of the PPACA requires the Secretary to establish standards for Navigators to ensure that Navigators are qualified, and licensed, if appropriate, to engage in the Navigator activities described in the statute. This provision has been implemented at § 155.210(b) (for all Exchanges) and at § 155.215(b) (for Navigators in FFEs).

Section 155.210(e)(9) specifies that an Exchange may require or authorize Navigators to provide assistance with a number of topics not specifically mentioned in the statute, including certain post-enrollment activities. This section specifies that Navigators operating in FFEs are authorized to provide assistance on these topics and are required to do so under Navigator grants awarded in 2018 or later.⁸⁴ To

provide more flexibility related to the required duties for Navigators operating in FFEs, we propose to amend § 155.210(e)(9) to make assistance with these topics permissible for FFE Navigators, not required, effective upon the awarding of the FEE navigator grants in 2019. We believe making assistance with these topics optional for FFE Navigators would reduce regulatory burden on FFE Navigator entities and better meet consumers' needs by allowing FFE Navigators to prioritize work according to consumer demand, community needs, and organizational resources.

We acknowledge that HHS added these duties 2 years ago to ensure the availability of more robust consumer assistance; however, since that time, there have been programmatic and health care coverage policy changes that have caused us to reflect further. We now believe that consumers will be better served by allowing more flexibility for Navigators to tailor their services to make the most of their resources and to fit the needs of their communities. For example, this change would allow FFE Navigators working with fewer resources to continue prioritizing providing help to consumers who are seeking to apply for and enroll in coverage over other permissible duties, such as the types of assistance listed at § 155.210(e)(9).

With this proposal, we want to emphasize that FFE Navigators would be authorized to continue to provide assistance with any of the topics listed under § 155.210(e)(9). Under the proposed approach, if FFE Navigator grantees choose to provide any of the assistance specified in § 155.210(e)(9), we would continue to expect them to assess their communities' needs and build competency in the assistance activities in which they are engaging. It is important to note that the current FFE Navigator training for annual certification or recertification might continue to include training on some of the § 155.210(e)(9) topics. To supplement the required FFE Navigator training, we also plan to continue providing FFE Navigators with additional information related to these assistance activities through informal webinars, newsletters, and technical assistance resources such as fact sheets and slide presentations. FFE Navigator grantees that opt to carry out any of the assistance activities in § 155.210(e)(9) will be expected to draw upon these

concepts and rights related to health coverage and how to use it; and, referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice on certain Exchange-related topics.

⁸² 81 FR at 12246.

⁸³ 83 FR at 16997.

⁸⁴ These topics are: Understanding the process of filing Exchange eligibility appeals; understanding and applying for exemptions from the individual shared responsibility payment that are granted through the Exchange; the Exchange-related components of the premium tax credit reconciliation process; understanding basic

materials to ensure their staff and volunteers are adequately prepared to provide that assistance. Our proposal would also retain SBE autonomy to determine whether requiring or authorizing the SBE's Navigators to perform the activities listed in § 155.210(e)(9) best meets the state's needs and resources.

We recognize that the time FFE Navigators currently spend providing assistance with the § 155.210(e)(9) topics varies.

To better understand the future impact of removing this requirement, we request comment on how many hours per month FFE Navigator grantees and individual Navigators currently spend providing the assistance activities described at § 155.210(e)(9), what percentage of their current work involves providing these types of assistance, and how that amount of work would be impacted if providing these types of assistance would no longer be required. We also request comment on how FFE Navigator grantees and individual Navigators might reprioritize work and spend time fulfilling their other duties, if not required to provide the types of assistance described under § 155.210(e)(9). Examples of how Navigators might elect to reprioritize work and fulfill other duties may include activities like helping consumers enroll in health coverage or conducting outreach and education in the community. We anticipate this may include many other activities.

In addition to proposing to increase FFE Navigator flexibility with regard to the types of assistance they provide, we also propose to provide more flexibility related to the training requirements that Exchanges establish for Navigators. Sections 155.210(b)(2) and 155.215(b)(2) establish Navigator training standards consistent with section 1311(i)(4) of the PPACA. Section 155.210(b)(2) specifies that Exchanges must develop and publicly disseminate a set of training standards to be met by all entities and individuals carrying out Navigator functions under the terms of a Navigator grant, to ensure expertise in several specific topic areas.⁸⁵ Currently, under § 155.210(b)(2), Exchanges (including SBEs) that opt to require their Navigators to perform the assistance described in § 155.210(e)(9) must also develop and disseminate training standards related to the specific

assistance areas they require under § 155.210(e)(9). Additionally Navigators in FFEs currently must be trained in fifteen additional topic areas identified at § 155.215(b)(2).⁸⁶

To provide more flexibility related to the training requirements for Navigators, we propose to streamline both the requirement in § 155.210(b)(2) for all Exchanges to develop and disseminate Navigator training standards on specific topics, and the list of required training topics for FFE Navigators in § 155.215(b)(2). We propose to amend the requirement at § 155.210(b)(2) to require Exchanges to develop and publicly disseminate training standards to ensure that the entities and individuals are qualified to engage in Navigator activities, including in the four major areas currently specified at § 155.210(b)(2)(i) through (iv). This proposal would eliminate the training requirements at current § 155.210(b)(2)(v)–(ix) that correspond to the activities outlined in § 155.210(e)(9), since under our proposal those activities would no longer be required. We also propose to replace the current list of fifteen additional FFE Navigator training topics at § 155.215(b)(2) with a cross-reference to the amended § 155.210(b)(2) topics.⁸⁷ We believe the revised regulations under this proposal would be broad enough to ensure that each Navigator program fulfills the requirements described in section 1311(i) of the PPACA.

We believe the revised regulations under this proposal would be broad enough to ensure that each Navigator program fulfills the requirements described in section 1311(i) of the PPACA.

This approach would provide Exchanges greater flexibility in

⁸⁶ These areas include: Information on QHPs, including benefits covered, differences among plans, payment process, rights and processes for appeals and grievances, and contacting individual plans; the tax implication of enrollment decisions; information on affordability programs; Exchange eligibility and enrollment rules and procedures; privacy and security standards, customer service standards; outreach and education methods and strategies; appropriate contact information for other agencies for consumers seeking information about coverage options not offered through the Exchange; basic concepts about health insurance and the Exchange; working effectively with individuals with limited English proficiency, and disabled, rural, underserved or vulnerable individuals; providing linguistically and culturally appropriate services; ensuring physical and other accessibility for people with a full range of disabilities; and applicable administrative rules, processes and systems related to Exchanges and QHPs.

⁸⁷ We note that § 155.215 also applies to non-Navigator assistance personnel, also referred to as enrollment assistance personnel. However, at this time, this program is no longer in operation in the FFEs.

designing their Navigator training programs to ensure coverage of the most instructive and timely topics and to align the training with future changes in the Navigator program or the operation of the Exchanges, while still ensuring that Navigators are qualified to carry out their required duties. This additional flexibility would also allow Exchanges to focus on training areas they determine to be most relevant to the populations they serve and on the policy and operations of the Exchange in which they operate.

Furthermore, Exchanges could opt to provide more training than would be required under these proposed amendments. For example, in addition to the FFE annual Navigator training, required for Navigator certification under § 155.215(b), Navigators in FFEs are provided with training throughout the year that serves as a supplement to the annual FFE Navigator training by covering timely and appropriate training topics that might not be included in the annual FFE Navigator training. This additional training provided by FFEs, is consistent with the requirement that FFE Navigators obtain continuing education, as specified at § 155.215(b)(1)(iv), and we intend to continue this practice.

Currently, HHS provides SBEs, including SBE-FPs, the flexibility to decide whether they will require or authorize their Navigators to provide assistance on any or all of the areas described at § 155.210(e)(9). Nothing in our proposals would change that flexibility. If SBEs choose to authorize or require their Navigators to provide assistance in any of the areas listed at § 155.210(e)(9), they would still be required to ensure that their Navigators are qualified to provide this assistance.

However, under our proposed amendments, any SBEs opting to authorize or require their Navigators to provide any or all of the types of assistance listed at § 155.210(e)(9) would have the flexibility to determine effective approaches to training their Navigators on performing these types of assistance based on local experience. We believe each Exchange is best positioned to determine the training that is most appropriate for the activities of their Navigators.

These proposals are intended to increase program flexibility within Exchanges and decrease regulatory burden related to Navigator training while maintaining standards that will ensure that Navigators are sufficiently prepared to carry out all required or authorized activities. We solicit comments on these proposals.

⁸⁵ These areas include: The needs of underserved and vulnerable populations; eligibility and enrollment rules and procedures; the range of QHP options and insurance affordability programs; and, the privacy and security standards applicable under § 155.260.

Finally, we also propose allowing, but not requiring, Navigators to assist consumers with applying for eligibility for insurance affordability programs and QHP enrollment through web-broker websites under certain circumstances. For a discussion of the provisions of this proposed rule related to that proposal, please see the preamble to § 155.220.

c. Standards Applicable to Navigators and Non-Navigator Assistance Personnel Carrying Out Consumer Assistance Functions Under §§ 155.205(d) and (e) and 155.210 in a Federally-Facilitated Exchange and to Non-Navigator Assistance Personnel Funded Through an Exchange Establishment Grant (§ 155.215)

For a discussion of the provisions of this proposed rule related to standards applicable to Navigators subject to § 155.215, please see the preamble to § 155.210.

d. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220).

Throughout the preamble for §§ 155.220 and 155.221, we propose to use the term “web-broker” to refer to an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with the selection and enrollment in QHPs offered through the Exchange, a process referred to as direct enrollment. We have used the term web-broker in the preamble of prior rules, as well as in guidance, and are proposing to generally replace that informal definition with the one proposed in this rulemaking.⁸⁸ In this proposed rule, as described further below, we propose to define web-broker in § 155.20 and to use that term in §§ 155.220 and 155.221, where applicable, to avoid confusion. We clarify that general references to agents or brokers would also be applicable to web-brokers when a web-broker is a licensed agent or broker. We are also proposing to define “direct enrollment technology providers” as a type of web-broker that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is

owned by, an agent or broker to provide technology services to facilitate participation in direct enrollment as a web-broker under §§ 155.220(c)(3) and 155.221. The proposed definition of web-broker reflects the inclusion of direct enrollment technology providers. Therefore, references to web-brokers are intended to include direct enrollment technology providers, as well as licensed agents or brokers that develop and host non-Exchange websites to facilitate QHP selection and enrollment, unless indicated otherwise. Please see the below preamble discussion related to § 155.221 for further details.

As described in the preamble to § 155.221, we are proposing significant changes to § 155.221 to streamline and consolidate the requirements applicable to all direct enrollment entities—both issuers and web-brokers—in one regulation. To reflect these changes, we also propose several amendments to § 155.220. First, we propose to move certain requirements that apply to all direct enrollment entities from § 155.220 to § 155.221. Specifically, we propose to move the requirements currently captured in § 155.220(c)(3)(i)(K) and (L), and to amend the requirement currently in (L), which as described further below, are proposed at § 155.221(b)(4) and (d), respectively.

We propose conforming edits throughout § 155.220 to incorporate the use of the term “web-broker,” as proposed to be defined in this rule, in applicable paragraphs to more clearly identify which FFE requirements extend to web-brokers. In the introductory text to paragraphs (a), (c), and (d), and in paragraphs (c)(1), (c)(5), (e), (f)(1), (f)(2), (f)(3), (f)(3)(i), (f)(4), (g)(1), (g)(2), (g)(2)(iii), (g)(2)(iv), (g)(4), (g)(5)(i)(A), (g)(5)(i)(B), (g)(5)(ii), (g)(5)(iii),⁸⁹ (h)(1), (h)(2), (h)(3), (i), (j)(1), (j)(3), (k)(1), (k)(2), and (l), we propose to add a reference to web-broker each time agents or brokers are referenced, in order to clarify that these paragraphs also apply to all web-brokers, including direct enrollment technology providers. In paragraphs (c)(3)(i), (c)(3)(i)(A), (c)(3)(ii), (c)(4), (c)(4)(i), (c)(4)(i)(E), (c)(4)(i)(F), and (c)(4)(ii), we propose to replace some references to “agent or broker” with a reference to “web-broker” to clarify when these paragraphs apply to only web-brokers, and not to other types of agents or

brokers who do not host or develop a non-Exchange website to assist consumers with direct enrollment in QHPs offered through the FFEs or SBE-FPs. We also propose to revise the section heading for § 155.220 to “Ability of States to permit agents, brokers, and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs”, as well as the section heading for paragraph (i) to similarly add a reference to web-broker. Please see the preamble discussion related to § 155.221 for further details on other proposed changes related to streamlining these regulations and clarifying the requirements applicable to web-brokers and other direct enrollment entities.

We also propose to amend § 155.220(c)(3)(i) to add a new paragraph (c)(3)(i)(K) that requires web-broker websites to comply with the applicable requirements in § 155.221 when an internet website of a web-broker is used to complete the QHP selection. We note that this new proposed requirement would also apply when an internet website of a web-broker is used to complete the Exchange eligibility application, through the existing cross reference to paragraph (c)(3)(i) in paragraph (c)(3)(ii)(A), but the applicable requirements under § 155.221 may differ depending on whether the non-FFE website is used to complete the Exchange eligibility application or is used to complete the QHP selection. Please see the below preamble discussion related to § 155.221 for further details.

We also propose to amend § 155.220(c)(3)(i) to add a new requirement at new paragraph (c)(3)(i)(L) that prohibits web-broker websites from displaying recommendations for QHPs based on compensation the web-broker, agent, or broker receives from QHP issuers. The term “compensation” includes commissions, fees, or other incentives as established in the relevant contract between an issuer and the web-broker. Web-broker websites often ask for certain information from consumers to assist with the display and sorting of QHP options on their non-Exchange websites. This may include estimated annual income, preferences regarding health care providers, prescription drugs the consumer takes, expected frequency of doctors’ visits, or other information. Web-brokers sometimes display QHP recommendations or assign scores to QHPs using the information they collect. We support the development and use of innovative consumer-assistance tools to help consumers shop for and select QHPs

⁸⁸ HHS currently defines the term “web-broker” as including an individual agent or broker, a group of agents and brokers, or a company that is interested in providing a non-Federally-facilitated Exchange website to assist consumers in the QHP selection and enrollment process as described in 45 CFR 155.220(c)(3).

⁸⁹ We also propose minor technical edits to the last sentence of paragraph (g)(5)(iii) to more closely align this provision with the language at paragraph (g)(4), which establishes similar parameters following the termination of an agent’s, broker’s, or web-broker’s agreements and registration with the Federally-facilitated Exchanges.

that best fit their needs, consistent with applicable requirements. However, we believe such recommendations should not be based on compensation web-brokers, agents, or brokers may receive from QHP issuers when consumers enroll in QHPs offered through Exchanges using web-broker non-Exchange websites.

We also propose to amend § 155.220(c)(4)(i)(A) to require a web-broker to provide HHS with a list of the agents or brokers who, through a contract or other arrangement, use the web-broker's non-Exchange website to assist consumers with completion of QHP selection and/or for the Exchange eligibility application, in a form or manner to be specified by HHS. The authority currently exists for HHS to request this information for agents or brokers who, through a contract or other arrangement, use the non-Exchange website to complete the QHP selection process.⁹⁰ However, due to the trend of increased use and expansion of direct enrollment pathways for QHP enrollment, we believe it is appropriate to collect this information proactively and to also extend its collection to include the use of web-broker non-Exchange websites for completion of the Exchange eligibility application, so that we may investigate and respond more efficiently and effectively to any potential instances of noncompliance that may involve agents or brokers using a web-broker's direct enrollment pathway. Having this information will, for example, enable us to identify more quickly whether noncompliance is attributable to a specific individual or individuals, instead of the web-broker entity. We anticipate issuing further guidance on the form and manner for these submissions and are considering requiring the list must include, at minimum, each agent's or broker's name, state(s) of licensure, and National Producer Number. We are considering adopting quarterly or monthly submission requirements, except for the month before the individual market open enrollment period and during the individual market open enrollment period, during which we are considering adopting weekly or daily submission requirements. We are considering requiring the submission of this data via email using an encrypted file format, such as a password-protected Excel spreadsheet, or alternatively requiring submission through a secure portal. We invite comments on the frequency and manner for these submissions, as well as other data elements that we should consider

for inclusion as part of this required reporting. We also propose to remove the final clause in § 155.220(c)(4) that limits the scope of that section to agents or brokers using web-broker websites who are listed as the agent of record on the enrollments. Several years of experience observing web-broker operations has informed us that web-brokers often submit an entity-level National Producer Number for all QHP enrollments completed through their websites. Therefore the web-broker business entity is the agent of record. However, the requirements stated in § 155.220(c)(4) are intended to apply broadly to agents or brokers using web-broker non-Exchange websites to assist with QHP selections and enrollments. We believe the existing requirements for web-brokers that provide access to their non-Exchange websites to other agents and brokers, such as verifying agents or brokers are licensed in the states in which they are assisting consumers and have completed the FFE registration process (see § 155.220(c)(4)(i)(B)), as well as reporting to HHS and applicable state departments of insurance any potential material breaches of applicable § 155.220 standards (see § 155.220(c)(4)(i)(E)), should apply broadly to agents and brokers using web-broker non-Exchange websites, and not only to those listed as the agents of record.

Currently, § 155.20 defines an "agent or broker" as a person or entity licensed by the state as an agent, broker, or insurance producer. Under § 155.220(d), an agent or broker that enrolls individuals in QHPs in a manner that constitutes enrollment through the Exchange or assists individuals with applying for APTCs or cost-sharing reductions must execute an agreement with the Exchange, register with the Exchange, receive training, and comply with the Exchange's privacy and security standards. When these regulatory provisions were originally drafted, it was anticipated that agents and brokers were predominantly individuals. However, with the expansion of direct enrollment, there are more FFE agents and brokers, including web-brokers, that have obtained FFE registration in their capacities as licensed business entities, and not in their individual capacities as licensed agents or brokers (non-individual entities). Certain regulatory requirements, such as those regarding training are less suited for these non-individual types of licensed agents or brokers. For example, to comply with the requirement to complete training at § 155.220(d)(2), we currently require

agents or brokers that are registered with the FFEs as non-individual entities to designate an individual to take training on the entity's behalf, even though all individual agents or brokers assisting FFE consumers through the entity have to complete the training as individual agents and brokers. Because the training is not designed for representatives of a non-individual entity who are not providing direct assistance to FFE consumers, we believe it would be appropriate to remove this requirement for licensed agent or broker non-individual entities. Therefore, we propose to amend § 155.220(d)(2) to exempt from the training requirement a licensed agent or broker entity that registers with the FFE in its capacity as a business organized under the laws of a state, and not as an individual person. HHS does not intend for this change to alter the requirement that individual agents or brokers must complete training, as applicable, as part of the annual FFE registration process. Therefore, all individual agents and brokers interacting with individual market FFE or SBE-FP consumers, whether working independently or with a non-individual agent or broker entity, including web-brokers, would continue to be required to complete annual training. Individual agents or brokers interacting with FFE-SHOP or SBE-FP-SHOP consumers would continue to be encouraged to take FFE training on an annual basis. We also propose to include language in § 155.220(d)(2) to clarify that direct enrollment technology providers would not be required to complete FFE annual training because these non-individual entities would not be interacting with individual market FFE or SBE-FP consumers without the assistance of an individual agent or broker; they are another example of a non-individual entity for which this training requirement is less suited.

To improve program integrity, we also propose to delete the existing § 155.220(g)(3) and add new paragraphs (g)(3)(i) and (ii) to allow HHS to immediately terminate an agent's or broker's agreement with the FFEs for cause with notice to the agent or broker if an agent or broker fails to comply with the requirement to maintain the appropriate license under state law in every state in which the agent or broker actively assists consumers with selecting or enrolling in QHPs offered through the FFEs or SBE-FPs. The FFE agreements required under §§ 155.220(d) and § 155.260(b) that agents and brokers execute with the FFEs as part of the annual FFE registration process includes the

⁹⁰ See 45 CFR 155.220(c)(4)(i)(A).

requirement to maintain valid licensure in every state that the agent or broker assists Exchange consumers. State licensure as an agent, broker, or insurance producer is a critical consumer protection to ensure that when assisting Exchange consumers these individuals and entities are familiar with rules and regulations applicable in all states in which they provide assistance to FFE or SBE-FP consumers. Licensure in every state where the agent or broker is actively assisting FFE or SBE-FP consumers is a predicate requirement to registering with the FFEs to provide such assistance. Allowing for immediate termination of an agent's or broker's agreements with the FFEs for failure to adhere to the applicable state licensure requirements ensures that an unlicensed individual may not continue to possess the agent/broker role that enables access to the FFEs or SBE-FPs to provide assistance to Exchange consumers as an agent or broker during the advance 30-day notice period that would otherwise apply under the current § 155.220(g)(3). We believe that allowing for immediate termination in these circumstances is appropriate to protect consumers, as well as Exchange operations and systems. Under this proposal, we would confirm information about licensure (or the lack thereof) with the applicable state regulators prior to taking action under the new proposed paragraph (g)(3)(ii). In addition, we propose that an agent or broker whose agreement(s) with the FFEs are immediately terminated for cause under the new proposed paragraph (g)(3)(ii) would be able to request reconsideration under § 155.220(h). We further propose amendments to paragraph (g)(4), such that, consistent with other terminations for cause under paragraph (g)(3), immediate terminations under the new proposed paragraph (g)(3)(ii) would result in the agent or broker not being registered with the FFEs or permitted to assist with or facilitate enrollment of qualified individuals, qualified employers or qualified employees in QHPs through the FFEs or SBE-FPs or assist individuals in applying for APTC and cost-sharing reductions (CSRs) for QHPs after the applicable period has elapsed. However, the agent or broker would be required to continue to protect any personally identifiable information accessed during the term of his or her or its agreements with the FFEs. We also propose to create a new paragraph (g)(3)(i) to retain the existing language describing the current notification process and timelines for termination for cause under paragraph (g) with

advance 30-days' notice, except that we propose a clarifying edit to reflect that the proposed paragraph (g)(3)(ii) would constitute an exception to the current process described in existing paragraph (g)(3). As detailed earlier in this preamble, we also propose to add a reference to web-broker to the existing paragraph (g)(3) (proposed as new paragraph (g)(3)(i)) to clarify this paragraph also applies to web-brokers.

To promote information technology system security in the FFEs and SBE-FPs, including the protection of consumer data, we are proposing to amend § 155.220(k) by adding a new paragraph (k)(3) that would continue to allow HHS to immediately suspend an agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction. This proposed language is identical to an existing provision that applies when an internet website of an agent or broker is used to complete QHP selection at current § 155.220(c)(3)(i)(L)⁹¹ and a similar provision applicable to QHP issuers participating in direct enrollment at current § 156.1230(b)(1).⁹² In proposed § 155.220(k)(3), we intend for this provision to apply to agents and brokers who, once registered under § 155.220(d)(1), obtain credentials that provide access to FFE systems that may be misused in a manner that threatens the security of the Exchange's operations or information technology systems. We believe this proposed change is necessary to ensure that HHS can continue to take immediate action to stop unacceptable risks to Exchange operations or systems posed by agents and brokers. Because the potential risks posed by agents and brokers with access to FFE systems are similar to those posed by web-brokers or QHP issuers participating in direct enrollment, we believe this change is necessary and appropriate to provide a uniform process and ability to protect Exchange systems and operations from unacceptable risks, as well as to protect sensitive consumer data. We note that agents and brokers whose ability to

⁹¹ This provision also currently applies when an internet website of an agent or broker is used to complete the Exchange eligibility application through the existing cross reference to paragraph (c)(3)(i) in § 155.220(c)(3)(ii)(A).

⁹² As described elsewhere in this rule, we propose to delete §§ 155.220(c)(3)(i)(L) and 156.1230(b)(1) and replace them with similar authority in proposed § 155.221(d) that would be applicable to all direct enrollment entities.

transact information with the Exchange is suspended under this proposed authority would remain registered with the FFEs and authorized to assist consumers using the Marketplace (or side-by-side) pathway,⁹³ unless and until their agreements were suspended or terminated under § 155.220(f) or (g).

To further improve program integrity, we are proposing in a new § 155.220(m) several additional areas in which we would propose to regulate web-brokers differently from agents or brokers. HHS believes these additional proposed changes in new paragraph (m) are important to further protect against potential fraudulent enrollment activities, including the improper payment of APTC and CSRs, to safeguard consumer data and Exchange operations and systems, and to ensure direct enrollment remains a safe and consumer-friendly enrollment pathway.

At § 155.220(m)(1), we propose to allow a web-broker's agreement(s) to be suspended or terminated for cause under § 155.220(g), or a web-broker to be denied the right to enter into agreements with the FFEs under § 155.220(k)(1)(i), based on the actions of its officers, employees, contractors, or agents. For example, if the actions of such individuals or entities are in violation of any standard specified in § 155.220, any terms or conditions of the web-broker's agreements with the FFEs, or any applicable federal or state statutory or regulatory requirements, whether or not the officer, employee, contractor, or agent is registered with the FFEs as an agent or broker, the web-broker's agreement(s) may be terminated under paragraph (g)(3) if HHS determines the specific finding of noncompliance or pattern of noncompliance is sufficiently severe. Similarly, if HHS reasonably suspects that an officer, employee, contractor, or agent of a web-broker may have engaged in fraud, whether or not such individual or entity is registered with the FFEs as an agent or broker, HHS may temporarily suspend the web-broker's agreement(s) for up to 90 days consistent with § 155.220(g)(5)(i)(A).

At § 155.220(m)(2), we propose to allow a web-broker's agreement to be suspended or terminated under § 155.220(g) or to deny it the right to enter into agreements with the FFEs under § 155.220(k)(1)(i), if it is under

⁹³ For more information on the Marketplace pathway, please see the Health Insurance Marketplace Guidance: Role of Agents, Brokers, and Web-brokers in Health Insurance Marketplace (November 8, 2016) Available at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Role-of-ABs-in-Marketplace_Nov-2016_Final.pdf.

the common ownership or control, or is an affiliated business, of another web-broker that had its agreement suspended or terminated under § 155.220(g). In general, for purposes of this provision, we propose to define “common ownership or control” based on whether there is significant overlap in the leadership or governance of the entities. We also propose to collect data during the web-broker onboarding process to assist with the analysis of whether the web-broker is under the common ownership or control, or is an affiliated business, of another web-broker that had its agreement suspended or terminated under § 155.220(g). At § 155.220(m)(3), we propose allowing the Exchange to collect information from a web-broker during its registration with the Exchange, or at another time on an annual basis, in a form and manner to be specified by HHS, sufficient to establish the identities of the individuals who comprise its corporate leadership and to ascertain any corporate or business relationships it has with other entities that may seek to register with the Federally-facilitated Exchange as web-brokers. These provisions are important to maintain program integrity, because they would provide authority to collect information that would be used to minimize the risk that an individual or entity can circumvent an Exchange suspension or termination or other enforcement action related to noncompliance.

As noted previously in this proposed rule, the use of direct enrollment through websites other than *HealthCare.gov* has expanded, as have the requirements on web-brokers seeking to participate in FFEs and SBE-FPs. For those reasons, we are also proposing to modify prior policy that prohibited Navigators and certified application counselors (CACs) (together referred to here as “assisters”) from using web-broker websites to assist with QHP selection and enrollment. Our proposal would permit, but not require, assisters in FFEs and SBE-FPs, to the extent permitted by state law, to use web-broker websites to assist consumers with QHP selection and enrollment, if the website meets certain conditions designed to ensure that assisters are able to use it while still meeting their statutory and regulatory obligations to provide fair, accurate, and impartial information and assistance to consumers. To promote state flexibility and autonomy under this proposal, SBEs other than SBE-FPs would have discretion to permit their assisters to use web-broker websites, so long as the web-broker websites that assisters are

permitted to use in SBEs, at a minimum, adhere to the standards outlined in this proposal. SBEs may instead choose to preserve the prohibition on assister use of web-broker websites.

Direct enrollment is a mechanism for third parties to directly enroll QHP applicants through a non-Exchange website in a manner considered to be through the Exchange, and web-brokers are a type of direct enrollment entity. Web-brokers have developed innovative tools to support consumers shopping for QHP coverage through their websites that assisters and the consumers they assist may find helpful when shopping for and enrolling in QHPs offered through Exchanges. Additionally, recently an enhanced form of direct enrollment has been implemented that provides new options for consumers to receive comprehensive services related to Exchange application and QHP enrollment, as well as year round support services through a non-Exchange website. Please see the preamble discussion related to § 155.221 for further details about direct enrollment and enhanced direct enrollment.

With the expansion of direct enrollment and the implementation of enhanced direct enrollment, both web-brokers and assisters have expressed interest in allowing assisters to use web-broker websites to assist consumers with selection and enrollment in QHPs offered through Exchanges. Because of the unique role assisters serve in many communities, some web-brokers have supported the idea of allowing assisters to facilitate selection and enrollment in QHPs offered through Exchanges using their non-Exchange websites to broaden the range of consumers these websites serve. Some web-brokers would also like to use assisters’ expertise in navigating more complex enrollment cases to provide additional support to the consumers they serve. Assisters have also expressed a desire to use web-broker websites to provide an improved consumer experience by leveraging innovative and unique consumer assistance tools and display features many web-brokers have developed. Additionally, some assisters have expressed a desire to have access to real-time information on the status of submitted applications and enrollments to more effectively assist consumers. Although we are not proposing to require web-brokers to develop assister portals at this time, so long as their sites meet the other proposed requirements described further below, some web-brokers may consider developing portals that would enable assisters to gain access to real-time information for each

of the consumers they assist using a web-broker’s website, similar to portals web-brokers may have already developed for affiliated agents and brokers.

The implementation of enhanced direct enrollment by some web-brokers also presents consumers with an additional method of applying for insurance affordability programs, selecting and enrolling in QHPs offered through Exchanges, and receiving post-enrollment support services. We believe this new option should be available to all FFE and SBE-FP assisters who provide application and enrollment assistance, provided that the information and assistance the assister provides would still remain fair, accurate, and impartial. And as previously stated, even when web-brokers have not yet implemented enhanced direct enrollment, we would like to provide assisters with the option to use the innovative and unique consumer-assistance tools and display features many web-brokers have developed to facilitate selection of QHPs offered through FFEs and SBE-FPs.

We also hope that allowing FFE and SBE-FP assisters to use web-broker websites to enroll consumers will encourage collaboration between assisters and web-brokers to the benefit of consumers by providing consumers the most appropriate support at each stage of the Exchange application and QHP selection and enrollment processes. We also believe that, moving forward, it is essential for assisters to evolve by collaborating with new partners to better accomplish the shared goals of educating consumers and helping them to enroll in QHPs offered through Exchanges that best fit their needs. We would also like to empower assisters to use tools that may be available outside of the *HealthCare.gov* platform that can best help assisters to serve their consumers and expand their reach and impact.

While we believe consumers working with assisters should have access to new options for selection and enrollment in QHPs offered through Exchanges that may be available through web-broker websites, we also want to ensure assisters working with consumers using these sites continue to comply with the statutory and regulatory standards governing their role and duties. Section 1311(i)(3)(B) and 1311(i)(5) of the PPACA and its implementing regulation at § 155.210(e)(2) require Navigators to provide fair, accurate, and impartial information to consumers in connection with their role as assisters. A similar requirement applies to CACs under § 155.225(c)(1). Under § 155.210(d),

Navigators are also prohibited from being a health insurance issuer or receiving any consideration directly or indirectly from any health insurance issuer in connection with the enrollment of any qualified individuals in a QHP. Finally, under § 155.210(b)(1) and (c)(1)(iv) (for all Navigators) and § 155.215(a) (for Navigators in FFEs) Navigators must be free from any prohibited conflicts of interest, including being a health insurance issuer or issuer of stop loss insurance; a subsidiary of a health insurance issuer or issuer of stop loss insurance; or an association that includes members of, or lobbies on behalf of, the insurance industry. Similarly, CACs are prohibited under § 155.225(g)(2) from receiving any consideration directly or indirectly from any health insurance issuer. These regulations ensure that assisters remain free from any influence that might interfere with their duty to provide consumers with the fair, accurate, and impartial information they need to make informed plan choices, while not influencing a consumer's ultimate QHP selection. We have previously interpreted the requirement to provide fair, accurate, and impartial information to mean that assisters are prohibited from using a web-broker's website to perform QHP application and enrollment assistance, unless the assister is using it as a reference tool to supplement the information available on *HealthCare.gov*.⁹⁴ This guidance was issued due to concerns that web-brokers are not required to provide fair, accurate, and impartial information, and are not prohibited from recommending specific products, including QHPs, to their clients. Therefore, we believed that assisters would be unable to use a web-broker website consistent with their duty to provide fair, accurate, and impartial information. Since then, we have required at § 155.220(j)(2)(i) that all agents and brokers (including web-brokers) enrolling consumers in QHPs offered through an Exchange in a manner considered to be enrollment through the FFEs provide consumers correct information, without omission of material fact, about QHPs and insurance affordability programs, and refrain from marketing or conduct that is misleading, coercive, or discriminatory. In addition, when a web-broker's non-Exchange website is used to facilitate QHP enrollment, it must provide consumers

⁹⁴ Information and Tips for Assistors: How and when to provide information about agent and broker services to consumers, and other information about engaging with agents and brokers. Available at <https://marketplace.cms.gov/technical-assistance-resources/agents-and-brokers-guidance-for-assistors.pdf>.

the ability to view all QHPs offered through the Exchange.⁹⁵

To ensure that assisters are meeting their statutory and regulatory obligations to provide fair, accurate, and impartial information and assistance to consumers when assisting them with selection and enrollment in QHPs offered through Exchanges using a web-broker website, we propose a number of additional standards in this rule that would have to be met by a web-broker's website for an assister to be able to use the site when assisting a consumer with an Exchange application or QHP selection and enrollment, to the extent permitted by state law. A web-broker interested in making its non-Exchange website available to assisters may obtain certification from the Exchange that its website meets these standards, but would not be required to obtain certification, so long as the standards are met.

First, we propose to replace § 155.220(c)(3)(i)(D) with a requirement at new paragraph (c)(3)(i)(D)(1) for web-broker websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), for such websites to be eligible for use by assisters when otherwise permitted under state law.⁹⁶ We note that web-brokers may obtain all QHP information they would be required to display in FFEs and SBE-FPs for assisters to be permitted to use their websites by integrating with the FFEs' Marketplace application programming interface (API). For FFEs and SBE-FPs, we are considering an optional annual certification process for web-brokers that would be integrated into the existing annual web-broker registration process, or could occur during another time of year, during which a web-broker could be certified by the Exchange by attesting to its compliance with the requirements proposed in new § 155.220(c)(3)(i)(D)(1). We propose to capture this optional annual certification process at new paragraph (c)(3)(i)(D)(2). We are also considering maintaining a public list of certified web-brokers in FFEs or SBE-FPs, so that assisters may more easily identify web-broker websites they may use in FFEs and SBE-FPs, when such arrangements

⁹⁵ See 45 CFR 155.220(c)(3)(i)(B). Also see 45 CFR 155.220(c)(3)(ii)(A).

⁹⁶ Under this proposal, web-brokers that do not make their websites available for assister use would remain subject to § 155.220(c)(3)(i)(A), which requires display of all QHP information provided by the Exchange and/or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and the prominent display of a standardized disclaimer provided by HHS to the extent that all of the required information is not displayed on the web-broker's website.

are permitted under state law. The proposed amendments to § 155.220(c)(3)(i)(D)(1) also provide that if a web-broker website does not facilitate enrollment in all QHPs, it would be required to identify to consumers the QHPs, if any, for which the web-broker website does not facilitate enrollment by prominently displaying a standardized disclaimer provided by the Exchange, in a form and manner specified by the Exchange, stating that the consumer can enroll in such QHPs through the Exchange website, and display a link to the Exchange website. We anticipate issuing further guidance on the form and manner for how the disclaimer should be displayed so that it is clearly associated with any QHPs for which the web-broker does not facilitate enrollment. We are considering whether the disclaimer or a link to the disclaimer should replace the link or other mechanism the web-broker would otherwise display to allow a consumer to proceed with selecting and enrolling in a QHP, or whether the disclaimer should be displayed in some other fashion. We invite comments on what requirements should be adopted in reference to how this disclaimer should be displayed on a web-broker's website.

We note assisters, as part of providing information that is fair, accurate, and impartial, are prohibited from steering consumers to choose particular plans or recommend enrollment in any plan. However, we also want to encourage web-brokers to provide innovative consumer assistance tools that could be used by assisters and the consumers they serve, including those related to displaying QHP recommendations that are based on consumer preferences or based on algorithms that take into account unique consumer characteristics, but that are not based on compensation that the web-broker, or an agent or broker that is assisting the consumer, may receive from QHP issuers. Therefore, in addition to requiring web-broker websites to display all QHP information provided by the Exchange and a standardized disclaimer if the non-Exchange website does not facilitate enrollment in all QHPs offered through the Exchange, we are considering the extent to which web-broker websites, when used by assisters, should be prohibited from making plan recommendations or otherwise reflecting a preference for certain plans over others. We also note that we are proposing at new § 155.220(c)(3)(i)(L) to prohibit web-broker websites from displaying QHP recommendations based on

compensation received from QHP issuers. For more information about the proposal to prohibit web-broker websites from displaying QHP recommendations based on compensation received from QHP issuers, please refer to the earlier preamble in § 155.220.

We acknowledge that the proposal at § 155.220(c)(3)(i)(L) does not prohibit web-brokers from otherwise implicitly making recommendations based on how they display QHPs. For example, web-brokers may implicitly recommend QHPs based on compensation they receive by listing those that are not offered by issuers with whom they have contractual agreements at the bottom of the listings of all QHPs offered through the Exchange. We have also considered if web-brokers wanting to make their websites available for assister use should be able to maintain existing pathways for agents and brokers or unassisted consumers that may include non-prohibited QHP recommendations by creating a separate assister pathway through which either no or limited QHP recommendations are made (whether implicitly or directly). We seek comment on this approach regarding display of QHP recommendations as it relates to the proposal to allow assisters to use web-broker websites subject to certain conditions and when otherwise permitted under state law.

We also believe that, for assisters to be permitted to use a web-broker website, there would need to be a mechanism to capture information about assisters assisting consumers with Exchange applications or QHP enrollment on the non-Exchange website and would need to transmit that data to the Exchange. However, in FFEs and SBE-FPs, web-brokers not participating in enhanced direct enrollment currently redirect consumers to *HealthCare.gov* to complete the eligibility application, and the eligibility application on *HealthCare.gov* includes fields to capture information about assisters and would therefore comply with such a requirement. For web-brokers in FFEs and SBE-FPs that offer an enhanced direct enrollment pathway, as indicated in operational guidance, specifically the Enhanced Direct Enrollment User Interface Question Companion Guide, the eligibility application must contain the same fields to capture information about assisters that are included in the application on *HealthCare.gov*. Therefore, we do not believe a regulatory change is required to accomplish this at this time, but clarify that, under our proposals related to use of web-broker websites by assisters, there would need to be a mechanism to

capture information about assisters assisting consumers with Exchange applications or QHP enrollment.

Nothing we are proposing is intended to change the prohibition at § 155.210(d)(4) on Navigators receiving any consideration, in cash, or in kind, directly or indirectly, from any health insurance issuer or issuer of stop loss insurance in connection with enrollment of any individuals or employees in a QHP or non-QHP, or on the parallel prohibition on CACs receiving any consideration directly or indirectly from any health insurance issuer or issuers of stop-loss insurance at § 155.225(g)(2). Therefore, if the proposed changes outlined above are implemented, all assisters using web-broker websites would continue to be prohibited from receiving compensation related to the assistance they provide with enrollments of consumers.

We seek comments on all of these proposals.

e. Standards for Third-Party Entities To Perform Audits of Agents, Brokers, and Issuers Participating in Direct Enrollment (§ 155.221)

Direct enrollment is a mechanism for third parties to directly enroll consumers seeking QHPs through a non-Exchange website in a manner considered to be through the Exchange. Direct enrollment was created to provide consumers different options to shop for and enroll in QHPs offered through the Exchange. The entities that are authorized to offer direct enrollment pathways to date are QHP issuers, as well as agents and brokers who develop and host non-Exchange websites to facilitate consumer selection of and enrollment in QHPs, referred to as web-brokers. As described in the preamble for § 155.220, we propose to use the term web-broker throughout this proposed rule when we are referring to agents and brokers who develop and host non-Exchange websites to facilitate consumer selection of and enrollment in QHPs offered through an Exchange, otherwise known as direct enrollment, as well as direct enrollment technology providers. The original version of direct enrollment, or classic direct enrollment, is still in operation. It utilizes a double redirect from a direct enrollment entity's website where QHP shopping occurs, to *HealthCare.gov* where the eligibility application is completed, and back to the entity's website to finalize the selection of the QHP. Classic direct enrollment allows QHP issuers and web-brokers who meet applicable requirements to design and host a plan shopping experience, and assist consumers with the QHP selection

process using relatively simple and limited application programming interfaces (APIs). The FFE direct enrollment program has expanded beyond the classic (that is, double-redirect) direct enrollment pathway as the FFEs' technical capabilities have significantly increased, beginning with proxy direct enrollment for plan year 2018⁹⁷ and continuing with the implementation of enhanced direct enrollment for plan year 2019 and beyond.⁹⁸ The requirements and technical expertise needed to participate in each new iteration of direct enrollment have similarly increased as participants have greater access to and responsibility for sensitive consumer data and Exchange systems. With enhanced direct enrollment, HHS allows participants to create and host a dynamic eligibility application and integrate several new APIs that facilitate eligibility determinations, as well as the consumer's enrollment in a QHP, and data sharing with the applicable Exchange. Enhanced direct enrollment provides new options for consumers to receive more comprehensive services through a non-Exchange website, without the need to redirect to *HealthCare.gov*, for application and enrollment and ongoing support throughout the plan year. We believe this will promote innovation and competition, and ultimately lead to better experiences for more consumers. We also believe streamlining and consolidating regulatory requirements, when possible, will simplify the otherwise complex requirements to participate in direct enrollment and make it easier for direct enrollment entities and organizations interested in participating in direct enrollment to understand and comply with applicable requirements. We also believe the complex and evolving nature of direct enrollment requires updates to accommodate innovation, ensure program integrity, and protect sensitive consumer data.

As mentioned previously, the entities that have been permitted to offer direct enrollment pathways to date have been QHP issuers and web-brokers that develop and host non-Exchange websites to facilitate selection and enrollment in QHPs offered through an FFE or SBE-FP. Direct enrollment regulatory provisions have likewise

⁹⁷ Proxy direct enrollment was implemented on a temporary basis for plan year 2018. More information is available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Guidance-for-the-Proxy-Direct-Enrollment-Pathway-for-2018-Individual-Market-Open-Enrollment-Period.pdf>.

⁹⁸ 81 FR at 94118.

been divided into sections that are separately applicable to QHP issuers participating in direct enrollment and web-brokers. As direct enrollment has evolved with the implementation of enhanced direct enrollment, many of the requirements applicable to QHP issuers performing direct enrollment and web-brokers have become increasingly similar. Therefore, we propose to revise § 155.221 to apply to all types of direct enrollment entities and to expand the requirements captured in this regulation beyond audits of direct enrollment entities. Further details are provided below. To reflect this change we propose to revise the section heading of § 155.221 to “Standards for direct enrollment entities and for third-parties to perform audits of direct enrollment entities.” We believe this approach would enhance clarity, reduce burdens, and better reflect an approach to direct enrollment that standardizes requirements across all entities participating in direct enrollment, where appropriate.

We propose to amend § 155.20 to include definitions of several terms we propose to use in § 155.221 including: “direct enrollment entity” and “web-broker.” Specifically, we propose to define “direct enrollment entity” as an entity that an Exchange permits to assist consumers with direct enrollment in QHPs offered through the Exchange in a manner considered to be through the Exchange as authorized by §§ 155.220(c)(3), 155.221, or 156.1230. We propose to define “web-broker” as an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in §§ 155.220(c)(3) and 155.221. As explained elsewhere in this preamble, we also propose to define the term “web-broker” to include direct enrollment technology providers. If this definition is finalized as proposed it would replace HHS’s current web-broker definition. We believe it is important to distinguish “web-brokers” from other agents and brokers utilizing a non-Exchange website to assist consumers with direct enrollment in QHPs offered through the Exchanges when they did not develop and do not host the non-Exchange website. Stated differently, agents and brokers using a non-Exchange website developed and hosted by a web-broker are not themselves necessarily web-brokers. For the reasons outlined in the preamble to

§ 155.220, we are of the view that it is appropriate to impose different requirements on web-brokers and agents and brokers who are not web-brokers. We believe this proposed definition and the proposed changes to §§ 155.220 and 155.221 outlined in this rulemaking reflect this approach and will enable web-brokers, agents, and brokers to more clearly identify when requirements are applicable to only web-brokers.

We also propose to amend § 155.20 to define “direct enrollment technology provider” as a type of web-broker business entity that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by, an agent or broker to provide technology services to facilitate participation in direct enrollment as a web-broker in accordance with §§ 155.220(c)(3) and 155.221. This definition is intended to capture instances when an individual agent or broker, a group of agents or brokers, or an agent or broker business entity, engages the services of or creates a technology company that is not licensed as an agent or broker, in order to assist with the development and maintenance of a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. When the technology company is not itself licensed as an insurance agency or brokerage, but otherwise is functioning as a web-broker would, we propose that these technology companies would be considered a type of web-broker that must comply with applicable web-broker requirements under §§ 155.220 and 155.221, unless indicated otherwise.⁹⁹ The proposed definition of “web-broker” reflects the inclusion of direct enrollment technology providers.

We propose to generally maintain the current requirements in § 155.221 that describe the standards for third-parties to perform audits of direct enrollment entities. However, to accommodate new content we are proposing to add to this regulation, we propose to redesignate the existing paragraphs (a) through (c) as paragraphs (e) through (g), respectively. We also propose some amendments to existing requirements currently captured in paragraphs (a) through (c), as described more fully below. In addition, throughout the redesignated paragraphs (e), (f), (f)(2), (f)(3), (f)(4),

⁹⁹ For example, proposed amendments to § 155.220(d)(2) would exempt direct enrollment technology providers from the training requirement that is part of the annual FFE registration process.

(f)(6), (f)(7), and (g), we propose conforming edits to change references to agents, brokers, and issuers to direct enrollment entities. We also propose to update the regulatory cross-references in the redesignated paragraph (f)(6) and (f)(7) from § 155.221(a) to § 155.221(e) to align with the streamlining changes proposed in this rulemaking. We also propose to add paragraph headings throughout this revised regulation for further clarity. In paragraph (e), we also propose to add language to require that the third-party entities that conduct annual reviews of direct enrollment entities to demonstrate operational readiness consistent with new proposed § 155.221(b)(4)¹⁰⁰ be independent of the entities they are auditing. We are proposing this change because we believe an independent audit is less likely to be influenced by a direct enrollment entity’s business considerations and therefore is more reliable. We note that current § 155.221(b)(4) requires third-party auditors to disclose to HHS any financial relationships they have with the entities they are auditing. We believe this disclosure requirement remains relevant even with the proposed addition to proposed paragraph (e) that would require auditors to be independent, because an auditor may be independent while also contracting with the entity it is auditing (and therefore having a financial relationship with the entity) to perform audits or other activities unrelated to those described in § 155.221. We therefore propose to retain this disclosure requirement at new § 155.221(f)(4). We also propose to clarify in paragraph (e) that an initial audit is required, in addition to subsequent annual audits, and that these audits must include review of the entity’s compliance with applicable direct enrollment requirements. These clarifications do not represent a change from the current approach, as direct enrollment entities are currently required to demonstrate operational readiness before their websites may be used to complete QHP selections,¹⁰¹ and these audits must confirm compliance with applicable requirements.¹⁰² In paragraph (e), we propose to add language to clarify that operational readiness must be demonstrated prior to

¹⁰⁰ Direct enrollment operational readiness review requirements are currently captured at 45 CFR 155.220(c)(3)(i)(K) for web-brokers and 45 CFR 156.1230(b)(2) for QHP issuers.

¹⁰¹ See 45 CFR 156.1230(b)(2) for issuers participating in direct enrollment and 45 CFR 155.220(c)(3)(i)(K) for web-brokers.

¹⁰² See 45 CFR 155.221(b)(5). Also see 45 CFR 156.1230(b)(2).

the direct enrollment entity's website being used to complete an Exchange eligibility application or make a QHP selection. This language is consistent with the operational readiness review requirements currently captured at § 155.220(c)(3)(i)(K) for web-brokers and § 156.1230(b)(2) for QHP issuers, which are proposed in this rulemaking to be moved to § 155.221(b)(4), and accounts for the fact that direct enrollment entities participating in enhanced direct enrollment will host the eligibility application in addition to QHP selection. Lastly, we propose to maintain the last sentence that currently appears in § 155.221(a) as the last sentence of the new paragraph (e) that states the third-party entity will be the downstream or delegated entity of the agent, broker, or issuer that participates or wishes to participate in direct enrollment, replacing the references to agent, broker, and issuer with direct enrollment entity. In paragraph (f), we propose to generally maintain the current requirement captured in § 155.221(b) that a direct enrollment entity must satisfy the requirement to demonstrate operational readiness by engaging a third-party entity that complies with the specified requirements. We also propose to require under new paragraph (f) that a written agreement must be executed between the direct enrollment entity and its auditor stating that the auditor will comply with the standards outlined in paragraph (f). We are proposing this new requirement because we believe the most effective way to ensure a direct enrollment entity has the necessary control and oversight over its auditor to ensure compliance with the applicable standards in § 155.221 is for those standards to be memorialized in a written agreement between the parties. We propose to delete the provision in current paragraph (c) that refers to each third-party entity having to satisfy the standards outlined in current paragraph (b), to avoid duplication with a nearly identical provision in proposed paragraph (f). The nearly identical provision in proposed paragraph (f), which, if finalized, would be the redesignated version of current paragraph (b), states that a third-party entity must execute an agreement with a direct enrollment entity under which the third-party entity agrees to comply with each of the standards in proposed paragraph (f). We otherwise propose to maintain, in the redesignated new paragraph (g), the provision that clarifies that direct enrollment entities may engage multiple third-party entities

to conduct the operational readiness audits under proposed § 155.221(e).

We propose a new paragraph (a) in § 155.221 that would establish the types of entities the FFEs will permit to assist consumers with direct enrollment in QHPs offered through an Exchange in a manner that is considered to be through the Exchange, to the extent permitted by state law. We propose to capture in § 155.221(a) the two types of entities that are already permitted by the FFEs to use and offer a non-Exchange website to facilitate direct enrollment: QHP issuers who meet the requirements in § 156.1230 and web-brokers who meet the requirements in § 155.220. New paragraph (a) also reflects that these entities would also be required to comply with the applicable requirements outlined in the new proposed § 155.221, which as described more fully above and below, we propose to capture the direct enrollment requirements that would apply to both web-brokers and QHP issuers participating in direct enrollment. For the remaining requirements that only apply to web-brokers or only apply to QHP issuers participating in direct enrollment, we propose to retain those requirements in §§ 155.220 and 156.1230, respectively.

We have issued guidance describing several existing display standards applicable to issuers or web-brokers participating in direct enrollment. Section 4.3 of the Federally-facilitated Marketplace and Federally-facilitated Small Business Health Options Program Enrollment Manual¹⁰³ states a QHP issuer's direct enrollment website should not include the offering of non-QHP health plans or non-QHP ancillary products (for example, vision or accident) alongside QHPs. It also states that QHP issuers should provide applicants the ability to search for off-Exchange products in a separate section of the website other than the QHP web pages, and that such plans may be marketed and displayed after the QHP selection process has been completed.

Guidance for Web-brokers Registered with the Federally-facilitated Marketplaces, released October 17, 2016,¹⁰⁴ established similar expectations for web-brokers. Section II.B states that web-brokers are expected

¹⁰³ Federally-facilitated Exchange and Federally-facilitated Small Business Health Options Program Enrollment Manual. Available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Enrollment-Manual-062618.pdf>.

¹⁰⁴ Guidance for Web-brokers Registered with the Federally-Facilitated Marketplaces (2016). Available at <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Guidance-Web-brokers-FFMs.pdf>.

to display QHPs and stand-alone dental plans offered through the applicable Exchange separately or in a manner that clearly distinguishes them from other available coverage options (for example, off-Exchange plans). It also provides that web-brokers should offer a QHP selection experience that is free from advertisements or information for other health insurance-related products and sponsored links promoting health insurance-related products.

We have received feedback from issuers and web-brokers that suggests there is some confusion about the current standards and guidance related to the display of QHPs and non-QHPs on non-Exchange websites used to facilitate direct enrollment. In an effort to clarify expectations, achieve greater uniformity in standards for all direct enrollment entities, and provide flexibility for innovation, we are proposing to establish requirements under § 155.221(b) for the FFEs, which would apply to all FFE direct enrollment entities. As noted elsewhere in preamble, some of the proposed requirements in § 155.221(b) are intended to streamline existing web-broker and QHP issuer direct enrollment requirements that are currently separately imposed under §§ 155.220 and 156.1230 by capturing these similar requirements in one regulation. Other proposed standards in § 155.221(b) are new regulatory requirements and are proposed to clarify or otherwise address compliance questions that have arisen under the existing regulations and guidance.

At new § 155.221(b)(1), we propose to require direct enrollment entities to display and market QHPs and non-QHPs on separate website pages on their respective non-Exchange websites. We believe this proposal balances the goals of minimizing consumer confusion about distinct products with substantially different characteristics, and allowing marketing flexibility and opportunities for innovation. At § 155.221(b)(2), we propose to require direct enrollment entities to prominently display a standardized disclaimer in the form and manner provided by HHS.¹⁰⁵ Consistent with current practice for the other standardized disclaimers provided by HHS under §§ 155.220 and 156.1230, we would provide further details on the text and other display details for the standardized disclaimer in guidance, but note its purpose would be to assist

¹⁰⁵ This new proposed standardized disclaimer would be in addition to the existing requirements at 45 CFR 155.220(c)(3)(i)(A) and (G) for web-brokers and at 45 CFR 156.1230(a)(1)(iv) for QHP issuers participating in direct enrollment.

consumers in distinguishing between direct enrollment entity website pages that display QHPs and those that display non-QHPs, and for which products APTCs and CSRs are available, during a single shopping experience. In new § 155.221(b)(3), HHS proposes that direct enrollment entities must limit the marketing of non-QHPs during the Exchange eligibility application and QHP plan selection process in a manner that would minimize the likelihood that consumers would be confused as to what products are available through the Exchange and what products are not. For example, under the proposed display standards captured at § 155.220(b)(1)–(3), direct enrollment entities would be required to offer an Exchange eligibility application and QHP selection process that is free from advertisements or information for non-QHPs and sponsored links promoting health insurance-related products. However, it would be permissible for a direct enrollment entity to market or display non-QHP health plans and other off-Exchange products in a section of the entity's website that is separate from the QHP web pages if the entity otherwise complied with the proposed standardized disclaimer requirements. In this example, the direct enrollment entity could begin marketing and displaying the non-QHP health plans and/or off-Exchange products after the consumer completes the Exchange eligibility application and QHP selection process, but before he or she has completed the shopping experience. The proposed requirements captured at § 155.221(b)(1)–(3) are intended to provide flexibility for direct enrollment entities to market valuable additional coverage that complements QHP coverage, while also allowing HHS to establish important parameters around the manner and type of non-QHPs that direct enrollment entities may market as part of a single shopping experience with QHPs. We believe marketing some products in conjunction with QHPs may cause consumer confusion, especially as it relates to the availability of financial assistance for QHPs purchased through the Exchanges. But we also appreciate that having flexibility to update these standards would allow us to adapt the display guidance as new products come to market and as technologies evolve that can assist with differentiating between QHPs offered through the Exchange and other products consumers may be interested in. We also believe that the convenience in being able to purchase additional products as part of a single shopping experience outweighs potential consumer confusion, if proper

safeguards can be put in place. We believe that the proposal at § 155.221(b)(3) would not unnecessarily constrain marketing by direct enrollment entities that takes place outside of the QHP application, selection, and enrollment experience as the proposal is specifically tailored to prohibit display and marketing of non-QHPs during the Exchange eligibility application and QHP selection process, but not during subsequent parts (if any) of the consumer shopping experience on the direct enrollment entity's website. In § 155.221(b)(4), we propose to move and consolidate the parallel requirements currently captured in §§ 155.220(c)(3)(i)(K) and 156.1230(b)(2) that web-brokers and QHP issuers, respectively, demonstrate operational readiness and compliance with applicable requirements prior to their internet websites being used to complete a QHP selection. We also include language in proposed § 155.221(b)(4) that would clarify that operational readiness and compliance with applicable requirements must also be demonstrated prior to their internet websites being used to complete an Exchange eligibility application. This clarification is important as enhanced direct enrollment is implemented and approved direct enrollment entities are hosting the Exchange eligibility application on their non-Exchange websites. We propose accompanying amendments to remove the operational readiness requirements from §§ 155.220 and 156.1230 as part of our efforts to streamline the regulatory requirements applicable to direct enrollment entities. Lastly, in § 155.221(b)(5), we propose to capture the requirement for direct enrollment entities to comply with all applicable federal and state requirements. This would include, but not be limited to, the additional Exchange requirements in §§ 155.220 and 156.1230 that apply to web-brokers and QHP issuers that participate in direct enrollment, respectively.

In § 155.221(c), we propose FFE requirements related to direct enrollment entity application assisters. Please see the preamble to § 155.415 for a discussion of these proposed requirements.

In § 155.221(d), we propose to consolidate and amend the existing parallel provisions in §§ 155.220(c)(3)(i)(L) and 156.1230(b)(1) to authorize HHS to immediately suspend the direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange

operations or Exchange information technology systems until such circumstances are resolved, remedied or sufficiently mitigated to HHS's satisfaction. We propose to remove the provisions from §§ 155.220(c)(3)(i)(L) and 156.1230(b)(1) as part of our efforts to streamline and consolidate the requirements applicable to direct enrollment entities in one regulation. The proposal captured in § 155.221(d) includes language that would extend the authority to suspend the ability to transact information with the Exchange to also include discovery of circumstances by HHS that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations. We believe this addition is necessary and appropriate as enhanced direct enrollment allows direct enrollment entities to collect and transmit the application data that the Exchanges use to complete eligibility determinations.

Lastly, to account for direct enrollment entities that may be assisting consumers in SBE-FP states, we are proposing a new § 155.221(h) to clarify that such entities are also required to comply with applicable standards in § 155.221.

We seek comment on all of these proposals.

f. Certified Application Counselors (§ 155.225)

We propose allowing, but not requiring, certified application counselors to assist consumers with applying for eligibility for insurance affordability programs and QHP enrollment through web-broker websites under certain circumstances. For a discussion of the provisions of this proposed rule related to that proposal, please see the preamble to § 155.220.

3. Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

a. Allowing Issuer Application Assisters To Assist With Eligibility Applications (§ 155.415)

In the first Program Integrity Rule,¹⁰⁶ we finalized § 155.415, which allows an Exchange, to the extent permitted by state law, to permit issuer application assisters to assist consumers in the individual market with an Exchange eligibility application if they met certain requirements. At § 155.20, we define issuer application assister as an employee, contractor, or agent of a QHP issuer who is not licensed as an agent,

¹⁰⁶ Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals; Final Rule, 78 FR 54070 (August 30, 2013).

broker, or producer under state law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs. At § 156.1230(a)(2), when permitted by an Exchange under § 155.415, and to the extent permitted by state law, we require QHP issuers that elect to use application assisters to ensure that each of their application assisters at least: (1) Receives training on QHP options and insurance affordability programs, eligibility, and benefits rules; (2) complies with the Exchange privacy and security standards consistent with § 155.260; and (3) complies with applicable state law related to the sale, solicitation, and negotiation of health insurance products, including laws related to agent, broker, and producer licensure, confidentiality, and conflicts of interest.

In adopting this approach, we recognized that, in some states, a license may be required to assist an applicant applying for an eligibility determination or redetermination. We deferred to existing state laws related to enrollment assistance when deciding which individuals may assist applicants and enrollees as authorized under § 156.1230(a)(2), and whether licensure would be required to provide such assistance. We stated that if state law requires a license to enroll applicants in coverage, then issuers and their application assisters would need to follow state law for licensure requirements. We also recognized that there were certain functions that issuers generally had their staff perform prior to the issuance of the first Program Integrity Rule, such as answering general information about plans, and we wanted to allow those individuals to continue to perform those functions, without meeting additional standards, if permitted by state law. We indicated that, if an issuer wants those individuals to perform additional functions, such as helping consumers as they apply for an eligibility determination or redetermination for coverage through the Exchange, or as they apply for insurance affordability programs, or as they report changes to an Exchange, those individuals could assist consumers with applications subject to the standards in § 156.1230(a)(2), so long as providing such assistance did not otherwise conflict with state law. Additionally, we stated that facilitating selection of a QHP may be a typical function of issuer staff and issuer staff would be able to perform post-eligibility functions such as plan compare and

selection, if permitted by state law, without being subject to the standards of § 156.1230(a)(2). As currently codified, the application assister definition and accompanying requirements only apply to issuer application assisters.

As described elsewhere in this rulemaking, we believe providing parity for direct enrollment entities, when possible, promotes fair competition and maximizes consumer choice. In addition, there is no apparent reason why issuer staff are more qualified to assist consumers with the Exchange eligibility application than the staff of other direct enrollment entities, assuming all receive appropriate training and when otherwise permitted under applicable state law. Therefore, we propose to expand the flexibility to employ or contract with application assisters to all direct enrollment entities, to create parity between issuers and other types of direct enrollment entities. Accordingly, we propose changes to several regulatory sections. Specifically, we propose to amend § 155.20 by adding the term “direct enrollment entity application assister,” which we propose to define as an employee, contractor, or agent of a direct enrollment entity who is not licensed as an agent, broker, or producer under state law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs. We propose to adopt the same approach for direct enrollment entity application assisters as the existing one for issuer application assisters. In other words, under our proposal, these application assisters would need to comply with applicable state law, including any licensure requirements, and we would continue to defer to existing state laws related to enrollment assistance when deciding which individuals may assist applicants and enrollees and whether licensure is required to provide such assistance.

We also propose to revise § 155.415(a) to authorize an Exchange, to the extent permitted by state law, to permit issuer and direct enrollment entity application assisters, as defined at § 155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and insurance affordability programs. Additionally, we propose to maintain language in § 155.415(a) to mandate that all direct enrollment entities who seek to use application assisters, and not just QHP issuers, must ensure that their application assisters meet the standards currently captured in § 156.1230(a)(2),

which we propose to move to new paragraphs (b)(1) through (3) of § 155.415, with two proposed amendments. Currently, § 156.1230(a)(2)(i) requires all QHP issuer application assisters to receive training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations. Licensed agents and brokers currently assisting consumers with QHP enrollment through the FFEs and SBE-FPs must have credentials to access FFE systems to offer that assistance. Those credentials are obtained during the FFE registration and training processes for agents and brokers. For application assisters to have similar access to FFE systems, so that they are also able to assist consumers as described above, they would need credentials similar to those obtained by agents and brokers during the FFE registration and training processes. Therefore, we propose to require that application assisters providing assistance in the FFEs and SBE-FPs complete a similar annual registration and training process as to what is required for agents and brokers under § 155.220(d)(1) and (2), in a form and manner to be specified by HHS, so that they would have the necessary training before being provided credentials to assist consumers. This proposed new training and registration requirement for application assisters is captured in the new proposed § 155.415(b)(1). Currently, § 156.1230(a)(2)(iii) requires all QHP issuer application assisters to comply with applicable agent, broker, and producer licensure laws, which may not be applicable in a given circumstance. For example, another state licensure law may exist for professionals whose functions are more similar to application assisters than licensed agents, brokers, and producers. We, therefore, propose to amend this standard (proposed to be redesignated at § 155.415(b)(3)) to require all application assisters to comply with applicable state law related to the sale, solicitation and negotiation of health insurance products, including any state licensure laws applicable to the functions to be performed by the application assister; confidentiality; and conflicts of interest. We are not proposing any changes to the other standard for application assisters that requires compliance with the Exchange’s privacy and security standards adopted consistent with § 155.260 (proposed to be redesignated from § 156.1230(a)(2)(ii) to new § 155.415(b)(2)). We also propose to delete and reserve § 156.1230(a)(2) to

reduce redundancies, as QHP issuers subject to the current standards captured at § 156.1230(a)(2) would be subject to the requirements in proposed § 155.415(b). We note that any QHP issuers that are not direct enrollment entities, but use application assisters, would also be subject to these proposed requirements and able to use application assisters, to the extent permitted by the applicable Exchange and state law. Finally, consistent with the proposed new paragraphs at § 155.221(c) and (h), we clarify that direct enrollment entities participating in FFEs and/or SBE-FPs would be permitted to use application assisters, to the extent permitted by state law.

We seek comment on these proposed changes.

b. Special Enrollment Periods (§ 155.420)

Under our current rules, individuals who are enrolled in employer-sponsored coverage or coverage purchased through an Exchange are eligible for a special enrollment period if they become newly eligible for APTC. However, no comparable special enrollment period exists for individuals who are enrolled in off-Exchange individual market coverage. We believe this may present a significant barrier for some individuals to remain in continuous coverage for the full plan year. Therefore, we propose to amend § 155.420(d) to add new paragraph (d)(6)(v) to authorize Exchanges, at their option, to provide a special enrollment period to enroll in Exchange coverage for off-Exchange individual market enrollees who experience a decrease in household income and receive a new determination of eligibility for APTC by an Exchange. We propose to make this special enrollment period available to qualified individuals and their dependents who experience circumstances that result in a decrease in household income if the qualified individual or his or her dependent are both (1) newly determined eligible for APTC by an Exchange, and (2) had MEC in which they were enrolled in and entitled to receive benefits under as described in 26 CFR 1.5000A-1(b) for one or more days during the 60 days preceding the change in circumstances. We cite 26 CFR 1.5000A-1(b) because it sets forth criteria for what it means to “have MEC,” including general requirements to be enrolled in and entitled to receive benefits under a program or plan identified as MEC in 26 CFR 1.5000A-2 and certain situations under which an individual is not enrolled in MEC but is treated as “having MEC.” Under this special

enrollment period, qualified individuals and dependents would be eligible for Exchange coverage following the regular prospective coverage effective date rules described in paragraph (b)(1) of this section, and must enroll within 60 days from the date of the financial change, in accordance with paragraph (c)(1) of this section.

We seek to provide individuals with more health coverage options and to empower them to enroll in the health coverage that best meets their needs and the needs of their families. For individuals and families with household incomes greater than 400 percent of the federal poverty level (FPL) who are not eligible for APTC, this may mean that they choose to purchase health insurance coverage outside of the Exchange during the annual open enrollment period or another eligible enrollment period, especially if the market outside of the Exchange offers additional plan options at more affordable prices. However, these individuals or families may experience a change in household income during the benefit year that makes their current health coverage no longer affordable. While paragraphs (d)(6)(iii) and (d)(6)(iv) currently provide special enrollment periods for individuals whose employer-sponsored coverage becomes unaffordable or does not meet minimum value, resulting in the employee becoming newly eligible for APTC, and for individuals previously in the coverage gap who become newly eligible for APTC as a result of a change in household income or move, respectively, there is no current pathway to Exchange coverage for enrollees in off-Exchange individual market plans who are newly eligible for APTC. Since no pathway to Exchange coverage currently exists, we believe that unsubsidized individual market enrollees whose household income has decreased may no longer be able to afford their unsubsidized health plans and may decide to terminate coverage mid-year. Therefore, the proposed special enrollment period in paragraph (d)(6)(v) would address this issue by establishing a pathway to Exchange coverage for qualified individuals enrolled in off-Exchange coverage who experience a decrease in household income and are newly determined eligible for APTC. We believe that this proposed policy would help promote continuous enrollment in health coverage and bring additional stability to the individual market risk pool, which would likely have a positive impact on health insurance premiums.

Individuals seeking to access the proposed special enrollment period

would not be current Exchange enrollees and would receive a new determination of eligibility for APTC through the Exchange’s consumer application. For the FFEs, an individual’s current household income and eligibility for APTC would be verified through the FFE’s eligibility system and data matching issue resolution process, in accordance with the requirements in § 155.320(c). To ensure that the proposed special enrollment period is available to the intended population while mitigating risks of adverse selection and inappropriate use, we propose to require the individual seeking access to the proposed special enrollment period to provide evidence of both a change in household income and of prior health coverage. Verifying that a decrease in household income occurred would prevent individuals who enrolled in health coverage off-Exchange, but have not experienced a financial change, from attempting to use this special enrollment period for the sole purpose of purchasing a more or less comprehensive level of coverage mid-year. To protect the individual market risk pool from adverse selection, as mentioned above, we propose to include a prior coverage requirement, which would protect against individuals who opted not to enroll in health coverage during the annual open enrollment period from using this special enrollment period to enroll in Exchange coverage mid-year. Additionally, this prior coverage requirement would promote continuous coverage. The proposed prior-coverage requirement aligns with existing prior-coverage requirements for special enrollment periods at § 155.420(d)(2)(i) and (d)(7). We envision leveraging existing pre-enrollment verification procedures¹⁰⁷ to confirm eligibility for the proposed special enrollment period, either through review of an individual’s submitted documentation or through use of electronic data sources, when available, prior to sending the individual’s plan selection to the issuer for enrollment. Consistent with current practices, in cases where eligibility is not verified electronically, individuals would be required to submit documentation within 30 days of plan selection to verify their prior coverage and their decrease in income. Consumer-submitted documents currently accepted by the FFE for

¹⁰⁷ Instructions for consumers to verify their eligibility for a special enrollment period are available at <https://www.healthcare.gov/coverage-outside-open-enrollment/confirm-special-enrollment-period/>.

purposes of demonstrating prior coverage and verifying attested income are currently available on *HealthCare.gov*,¹⁰⁸ and we anticipate developing additional consumer instructions around submitting documents to verify a decrease in income.

We recognize that State Exchanges maintain flexibility to determine whether and how to implement pre-enrollment verification of eligibility for special enrollment periods and may not have the operational capacity to immediately implement and verify eligibility for this special enrollment period. Some State Exchanges may also determine there is insufficient need among off-Exchange consumers for this special enrollment period because of the rating and pricing practices specific to their state markets. Therefore, we are proposing to make this special enrollment period available at the option of the Exchange.

This proposed special enrollment period is intended only for individuals not currently enrolled in Exchange coverage, since current Exchange enrollees who experience a decrease in household income mid-year may already qualify for a special enrollment period under paragraphs (d)(6)(i) and (ii), or may enroll in off-Exchange plans if they become newly ineligible for APTC under § 147.104(b)(2)(i)(B).

Paragraph (a)(4)(iii) of § 155.420 generally limits the plans into which an enrollee who qualifies for a special enrollment period or is adding a dependent through a special enrollment period may enroll. Several special enrollment periods are excluded from this limitation. However, we propose that the proposed new special enrollment period would be subject to the rule in paragraph (a)(4)(iii). Therefore, should a qualified individual who qualifies for the proposed special enrollment period in paragraph (d)(6)(v) already have members of his or her household enrolled in Exchange coverage and those enrollees do not qualify for another special enrollment period at the same time that provides them with additional plan enrollment flexibilities, the Exchange must allow the qualified individual to be added to the same QHP as the Exchange enrollees in his or her household, if the plan business rules allow. If the plan's business rules do not allow the qualified individual to enroll, the Exchange must allow the current enrollees to change to

another QHP within the same level of coverage (or one metal level higher or lower if no such QHP is available), and to add the qualified individual to the same plan as outlined under § 156.140(b). As always, and at the option of the qualified individual, he or she may enroll in a separate QHP at any metal level, in accordance with § 155.420(a)(4)(iii)(B). We anticipate that this situation will arise relatively infrequently due to the availability of the special enrollment periods at (d)(6)(i) and (d)(6)(ii) of § 155.420 for enrollees who become newly eligible for APTC or experience a change in eligibility for cost-sharing reductions.

We also propose to modify the types of coverage that may satisfy the prior coverage requirement by amending § 155.420(a)(5) to include the coverage types described in paragraphs (d)(1)(iii) and (iv) of this section, such as pregnancy Medicaid, CHIP unborn child, and Medically Needy Medicaid, in addition to MEC described in 26 CFR 1.5000A-1(b). We believe that this clarification is necessary to ensure consistency across our special enrollment period regulations for the types of coverage that qualify an individual for a special enrollment period. We already treat certain types of coverage, including pregnancy Medicaid, CHIP unborn child, and Medically Needy Medicaid, although not independently designated as MEC under 26 CFR 1.5000A-1(b), as MEC for purposes of qualifying for the loss of MEC special enrollment period described in § 155.420(d)(1). However, individuals currently enrolled in these types of coverage would not qualify for special enrollment periods that require prior coverage. To avoid treating the same types of coverage differently for purposes of eligibility for different special enrollment periods, we propose an aligning edit to paragraph (a)(5).

Lastly, we propose to clarify certain terms in § 155.420(b)(2)(iv), which addresses the coverage effective dates that apply to the special enrollment periods in § 155.420(d)(1), (d)(3), (d)(6)(iii), (d)(6)(iv), and (d)(7). Specifically, we propose to replace the word "consumer" with the phrase "qualified individual, enrollee, or dependent, as applicable," to align with the terminology used at § 155.420(d) to describe special enrollment period triggering events. We do not anticipate that this proposed wording change will create additional cost or burden for Exchanges or for any other stakeholders.

We seek comment on these proposals.

4. Eligibility Standards for Exemptions (§ 155.605)

a. Eligibility for an Exemption Through the IRS (§ 155.605(e))

Individuals can currently claim hardship exemptions through the tax filing process for hardships described in § 155.605(e)(1) through (4) which include most hardship exemptions, but not the general hardship types described in paragraph (d)(1) of this section. Allowing the general hardship exemption types to be claimed through the Internal Revenue Service (IRS) would increase flexibility and decrease burdens for individuals seeking hardship exemptions. Therefore, we propose to amend § 155.605(e), which describes the exemptions that can be claimed through the IRS tax filing process without an individual having to obtain an exemption certificate number from an Exchange, to add a new paragraph (e)(5) that will allow consumers to claim through the tax filing process hardship exemptions within all of the categories described in paragraph (d)(1) of this section on a federal income tax return for tax year 2018 only.

This proposal aligns with HHS guidance published September 12, 2018, entitled, "Guidance on Claiming a Hardship Exemption through the Internal Revenue Service (IRS)"¹⁰⁹ and with IRS Notice 2019-05.¹¹⁰ We anticipate that the guidance and this proposal would provide individuals with additional flexibility for claiming a hardship exemption by providing individuals the additional option of claiming this exemption on their federal income tax return for 2018 only.

We seek comments on this proposal.

b. Required Contribution Percentage (§ 155.605(d)(2))

Under section 5000A of the Code, an individual must have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under § 155.605(d)(2), an individual is exempt from the requirement to have MEC if the amount that he or she would be required to pay for MEC (the required contribution) exceeds a particular percentage (the required contribution percentage) of his or her projected household income for a year. Although the Tax Cuts and Jobs Act reduces the individual shared responsibility payment to \$0 for months beginning after December 31, 2018, the required

¹⁰⁸ Available at <https://www.healthcare.gov/help/prove-coverage-loss/> and <https://www.healthcare.gov/verify-information/documents-and-deadlines/>.

¹⁰⁹ <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf>.

¹¹⁰ <https://www.irs.gov/pub/irs-drop/n-19-05.pdf>.

contribution percentage is still used to determine whether individuals above the age of 30 qualify for an affordability exemption that would enable them to enroll in catastrophic coverage under § 155.305(h).

The initial 2014 required contribution percentage under section 5000A of the Code was 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and Treasury regulations at 26 CFR 1.5000A-3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period. The excess of the rate of premium growth over the rate of income growth is also used for determining the applicable percentage in section 36B(b)(3)(A) of the Code and the required contribution percentage in section 36B(c)(2)(C) of the Code.

As discussed elsewhere in this preamble, we are proposing as the measure for premium growth a 2020 premium adjustment percentage of 1.2969721275 (or an increase of about 29.7 percent over the period from 2013 to 2019). This reflects an increase of about 3.6 percent over the 2019 premium adjustment percentage (1.2969721275/1.2516634051). However, we note that this percentage increase does not reflect a comparison of identical premium measures, as it has in previous years, since we are proposing to incorporate individual market insurance premium growth in our calculation of the 2020 benefit year premium adjustment percentage.

As the measure of income growth for a calendar year, we established in the 2017 Payment Notice that we would use per capita personal income (PI). Under the approach finalized in the 2017 Payment Notice, using the National Health Expenditure Account (NHEA) data, the rate of income growth for 2020 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year (\$55,136 for 2019) exceeds per capita PI for 2013 (\$44,586), carried out to ten significant digits. The ratio of per capita PI for 2019 over the per capita PI for 2013 is estimated to be 1.2366213610 (that is, per capita income growth of about 24 percent). This reflects an increase of approximately 2.5 percent relative to the increase for 2013 to 2018 (1.2366213610/1.2059028167) used in the 2019 Payment Notice. Per capita PI includes government transfers, which refers to benefits individuals receive from federal, state, and local governments (for example, Social

Security, Medicare, unemployment insurance, workers' compensation, etc.).¹¹¹

Thus, using the 2020 premium adjustment percentage proposed in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2019 is 1.2969721275/1.2366213610, or 1.0488029468. This results in a proposed required contribution percentage for 2020 of $8.00 * 1.0488029468$ or 8.39 percent, when rounded to the nearest one-hundredth of one percent, an increase of 0.09 percentage point from 2019 (8.39042 – 8.30358). We seek comment on this proposal.

F. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. FFE and SBE–FP User Fee Rates for the 2020 Benefit Year (§ 156.50)

Section 1311(d)(5)(A) of the PPACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. In addition, 31 U.S.C. 9701 permits a federal agency to establish a charge for a service provided by the agency. If a state does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the PPACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), we specified that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year, and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP.

OMB Circular No. A–25R established federal policy regarding user fees; it specifies that a user fee charge will be assessed against each identifiable recipient of special benefits derived from federal activities beyond those received by the general public. Activities performed by the federal government that do not provide issuers participating in an FFE with a special benefit are not covered by this user fee. As in benefit years 2014 through 2019, issuers seeking to participate in an FFE in the 2020 benefit year will receive two

special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP. For the 2020 benefit year, issuers participating in an FFE will receive special benefits from the following federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

Based on estimated costs, enrollment, and premiums for the 2020 benefit year, we propose a 2020 benefit year user fee rate for all participating FFE issuers of 3.0 percent of total monthly premiums. This proposed rate is lower than the 3.5 percent FFE user fee rate that we had established for benefit years 2014 through 2019. The lower proposed user fee rate for the 2020 benefit year reflects our estimates of premium increases and enrollment decreases for the 2020 benefit year. We seek comment on this proposal.

As previously discussed, OMB Circular No. A–25R established federal policy regarding user fees, and specified that a user charge will be assessed against each identifiable recipient for special benefits derived from federal activities beyond those received by the general public. SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between state and federal programs. Accordingly, in § 156.50(c)(2), we specified that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, unless the SBE–FP and HHS agree on an alternative mechanism to collect the funds from the SBE–FP or state instead of direct collection from SBE–FP issuers. The benefits provided to issuers in SBE–FPs by the federal government include use of the federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs

¹¹¹ U.S. Department of Commerce Bureau of Economic Analysis (BEA) Table 3.12 Government Social Benefits. Available at https://apps.bea.gov/iTable/iTable.cfm?reqid=19&step=3&isuri=1&categories=survey&nipa_table_list=110.

and other applicable state health subsidy programs, as defined at section 1413(e) of the PPACA, and QHP enrollment functions under § 155.400. The user fee rate for SBE-FPs is calculated based on the proportion of FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE-FPs. Based on this methodology, we propose to charge issuers offering QHPs through an SBE-FP a user fee rate of 2.5 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE-FP. This proposed rate is lower than the 3.0 percent user fee rate that we had established for benefit year 2019. The lower proposed user fee rate for SBE-FP issuers for the 2020 benefit year reflects our estimates of premium increases and enrollment decreases for the 2020 benefit year. We seek comment on this proposal.

We will continue to examine contract cost estimates for the special benefits provided to issuers offering QHPs on the FFEs and SBE-FPs for the 2020 benefit year as we finalize the FFE and SBE-FP user fee rates, which will be reflected in the final rule.

2. Silver Loading

Section 1402 of the PPACA requires issuers to provide CSRs to help make coverage affordable for certain low- and moderate-income consumers who enroll in silver level QHPs, as well as Indians who enroll in QHPs at any metal level. Section 1402 of the PPACA further states that HHS will reimburse issuers for the cost of providing CSRs. Until October 2017, the federal government relied on the permanent appropriation at 31 U.S.C. 1324 as the source of funds for federal CSR payments to issuers. However, on October 11, 2017, the Attorney General of the United States provided HHS and the Department of the Treasury with a legal opinion indicating that the permanent appropriation at 31 U.S.C. 1324 cannot be used to fund CSR payments to insurers. In light of this opinion—and in the absence of any other appropriation that could be used to fund CSR payments—HHS directed CMS to discontinue CSR payments to issuers until Congress provides a valid appropriation. In response to the termination of CSR payments to issuers, many issuers increased premiums in 2018 and 2019 only on silver level QHPs to compensate for the cost of CSRs—a practice sometimes referred to as “silver loading” or “actuarial

loading.” Because premium tax credits are generally calculated based on the second-lowest cost silver plan offered through the Exchange, this practice has led to consumers receiving higher premium tax credits. These higher premium tax credits are being borne by taxpayers.

Silver loading is the result of Congress not appropriating funds to pay CSRs, with the result being an increase to the premiums of benchmark plans used to calculate premium tax credits, and the federal deficit.¹¹² The Administration supports a legislative solution that would appropriate CSR payments and end silver loading. In the absence of Congressional action, we seek comment on ways in which HHS might address silver loading, for potential action in future rulemaking applicable not sooner than plan year 2021.

3. Essential Health Benefits Package

a. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

In the 2019 Payment Notice, we finalized options for states to select new EHB-benchmark plans starting with the 2020 benefit year. Under 45 CFR 156.111, a state may modify its EHB-benchmark plan by:

- (1) Selecting the EHB-benchmark plan that another state used for the 2017 plan year;
- (2) Replacing one or more EHB categories of benefits in its EHB-benchmark plan used for the 2017 plan year with the same categories of benefits from another state's EHB-benchmark plan used for the 2017 plan year; or
- (3) Otherwise selecting a set of benefits that would become the state's EHB-benchmark plan.

Under any of these three options, the EHB-benchmark plan would also have to meet additional standards, including scope of benefits requirements. These options were intended to provide states with more flexibility in the selection of their EHB-benchmark plan than had previously existed. In the 2019 Payment Notice, we encouraged states to consider the potential impact on vulnerable populations as they select their new EHB-benchmark plans, and the need to educate consumers on benefit design changes. We also remind states to

inform issuers of such changes should they select a new EHB-benchmark plan.

We believe that the three new options—the third in particular—may provide states with additional flexibility to address the opioid epidemic. For example, Illinois made changes to its EHB-benchmark plan for plan year 2020 that aim to reduce opioid addiction and overdose by including in its EHB-benchmark plan alternative therapies for chronic pain, restricting access to prescription opioids, and expanded coverage of mental health and substance use disorder treatment and services.¹¹³ We encourage other states to explore whether modifications to their EHB-benchmark plan would be helpful in fighting the opioid epidemic.

Additionally, the 2019 Payment Notice stated that we would propose subsequent EHB-benchmark plan submission deadlines in the HHS annual Notice of Benefit and Payment Parameters. Accordingly, we propose May 6, 2019, as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2021 plan year.¹¹⁴ To give advance notice to states and issuers, we are simultaneously proposing May 8, 2020, as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2022 plan year. We recognize that these deadlines are earlier in the year than the July 2, 2018 deadline for the state's EHB-benchmark plan selection for the 2020 plan year. These deadlines would allow for an earlier finalization of a state's EHB-benchmark plan and a longer time period for issuers to develop plans that adhere to their state's new EHB-benchmark plan. We emphasize that these deadlines would be firm, and that states should optimally have one of their points of contact who have been pre-designated to use the EHB Plan Management Community reach out to us using the EHB Plan Management Community well in advance of the deadlines with any questions. Although not a requirement, we recommend states submit applications at least 30 days prior to the submission deadlines to ensure completion of their documents by the proposed deadlines. We also remind states that they must have completed the required public comment

¹¹² CBO estimates that, under current law, outlays for health insurance subsidies and related spending would rise by about 60 percent over the projection period, increasing from \$58 billion in 2018 to \$91 billion by 2028. See CBO report *The Budget and Economic Outlook: 2018 to 2028*, April 2018, page 51. Available at <https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53651-outlook.pdf>.

¹¹³ IL DOI Press Release, “Illinois becomes first and only state to change Essential Health Benefit-benchmark plan.” Aug. 27, 2018. Available at https://www2.illinois.gov/ISNews/18098-DOI_Essential_Health_Benefit-benchmark_plan_Release.pdf.

¹¹⁴ This would be delayed, if necessary, to be on or after the effective date of the 2020 Payment Notice Final Rule.

period and submit a complete application by the deadlines. We seek comment on these proposed deadlines.

b. Provision of EHB (§ 156.115)

In the 2019 Payment Notice, we also finalized a policy through which states may opt to permit issuers to substitute benefits between EHB categories. In the preamble to that rule, we stated that the deadlines applicable to state selection of a new benchmark plan would also apply to this state opt-in process. We therefore propose May 6, 2019 as the deadline for states to notify us that they wish to permit between-category substitution for the 2021 plan year and May 8, 2020 as the deadline for states to notify us that they wish to permit between-category substitution for the 2022 plan year. States wishing to make such an election must do so via the EHB Plan Management Community. We seek comment on these proposed deadlines.

c. Prescription Drug Benefits (§ 156.122)

At new § 156.122(d)(3), we propose that for plan years beginning on or after January 1, 2020, QHP issuers in the FFEs would be required to notify HHS annually in an HHS-specified format of any mid-year formulary changes made in the prior plan year consistent with the proposed changes to § 147.106(e). Under this proposal, QHP issuers in the FFEs would be required to report the name of the drug being removed from the formulary, dosage, name of the generic equivalent, the Rx Norm Concept Unique Identifier (RxCUI) associated with the brand and generic drug, if the brand drug was moved to a higher cost sharing tier or removed from the formulary, in a manner specified in the forthcoming PRA associated with this rule. We intend to use this information to understand how the proposed change would affect QHP enrollees. We seek comment on this proposal.

In addition to policies proposed above and at §§ 147.106 and 156.130, we are soliciting comments on two additional drug policies that would be intended to consider the potential of therapeutic substitution. First, the prescription drug market became more efficient after several states passed laws that allowed for generic substitution. Similarly, therapeutic substitution, which consists of substituting chemically different compounds within the same class for one another,¹¹⁵ could be employed to improve the efficiency of the pharmaceutical market. We

acknowledge that many stakeholders are opposed to therapeutic substitution and that there are concerns regarding efficacy, adverse effects, drug interactions, and different indications for drugs within a class. If therapeutic substitution were to become commonplace, efficient systems that allow for seamless communication among prescribers, pharmacies, and insurance companies would need to be in place. Therapeutic substitution may help decrease drug costs if it can be implemented in a way that does not negatively affect quality and access to care. We solicit comment on whether therapeutic substitution and generic substitution policies should both be pursued since each of the two options might offset any potential premium impact of the other, as well as whether certain drug categories and classes are better suited to therapeutic substitution than others. We are also interested in comments on any existing standards of practice for therapeutic substitution and whether those standards are nationally recognized and readily available for providers to use.

Second, the majority of issuers, employers, and pharmaceutical benefit managers negotiate price discounts and rebates from pharmaceutical manufacturers by implementing tiered formularies, which link patients' cost-sharing obligation to the price of each drug. Tiered formularies have been successful in attenuating the growth in pharmaceutical spending and overall drug spending. However, in recent years, drug spending has again increased. Reference-based pricing is one strategy for attenuating increases in pharmaceutical spending. Reference-based drug pricing occurs when an issuer in a commercial market covers a group of similar drugs, such as within the same therapeutic class, up to a set price, with the enrollee paying the difference in cost if the enrollee desires a drug that exceeds the set (reference) price.¹¹⁶ Implementation of reference-based pricing for drugs could bring down overall health plan costs, and perhaps premium increases, while increasing consumer out-of-pocket costs in some instances. Durable medical equipment benefits like eyeglasses and contacts are sometimes covered in a similar manner. Although reference-based pricing is often discussed in the context of network adequacy and using certain providers within a particular

network who are willing to accept a reference price, we do not intend for this drug policy to have network implications, and issuers are currently free to impose lower cost sharing for drugs obtained via mail order. We seek comment on the opportunities and risks of implementing or incentivizing reference-based pricing for prescription drugs.

d. Prohibition on Discrimination (§ 156.125)

Opioid misuse and addiction is a serious national crisis that affects public health, as well as social and economic welfare. More than 115 people in the United States die each day from opioid overdoses.¹¹⁷ The Centers for Disease Control and Prevention estimates that the total costs of prescription opioid misuse alone in the United States is \$78.5 billion per year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement.¹¹⁸ It has been an active Public Health Emergency, as determined by the Secretary under 42 U.S.C. 247d, since October 26, 2017.¹¹⁹

Several factors have influenced the opioid crisis, including: The opioid pharmaceutical manufacturing and supply chain industry; deficient patient and provider pain management education; rogue pharmacies and unethical physician prescribing; and the insufficient availability of treatment services, including Medication-Assisted Treatment (MAT).¹²⁰

¹¹⁷ CDC/NCHS, National Vital Statistics System, Mortality. CDC Wonder, Atlanta, GA: US Department of Health and Human Services, CDC; 2017. <https://wonder.cdc.gov>.

¹¹⁸ Florence GS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Med Care*. 2016; 54(10):901–906. doi:10.1097/MLR.0000000000000625. Available at <https://www.ncbi.nlm.nih.gov/pubmed/27623005>.

¹¹⁹ As determined by Acting Secretary Eric D. Hargan. "Determination that a Public Health Emergency Exists". October 26, 2017. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioids.aspx>. Renewed by Acting Secretary Hargan. "Renewal of Determination that a Public Health Emergency Exists". January 19, 2018. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-24Jan2018.aspx>. Renewed by Secretary Alex M. Azar II. "Renewal of Determination that a Public Health Emergency Exists". April 20, 2018. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-20Apr2018.aspx>. Renewed by Secretary Azar. "Renewal of Determination that a Public Health Emergency Exists". July 19, 2018. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-19July2018.aspx>. Renewed by Secretary Azar. "Renewal of Determination that a Public Health Emergency Exists". October 18, 2018. Available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/opioid-18Oct2018.aspx>.

¹²⁰ "The President's Commission on Combating Drug Addiction and the Opioid Crisis". Pages 19–

¹¹⁵ Pengxiang, L., Sanford Shwartz, J., & Doshi, J.A. (2016). Impact of Cost Sharing on Therapeutic Substitution: The Story of Statins in 2006. *Journal of the American Heart Association*.

¹¹⁶ Robinson, J.C., Whaley, C.M., & Brown, T.T. (2017). Association of Reference Pricing with Drug Selection and Spending. *New England Journal of Medicine*, 377:658665. Doi:10.1065/NEJMsa1700087.

MAT is any treatment for opioid use disorder that includes a medication approved by the Food and Drug Administration for opioid addiction detoxification or maintenance treatment.¹²¹ MAT has proven to be clinically effective in treating opioid use disorder and to significantly reduce the need for inpatient detoxification services for individuals with opioid use disorder.¹²²

Despite this evidence, and despite the attention paid to the nationwide opioid Public Health Emergency, there is not comprehensive, nationwide coverage of the drugs used in MAT, at least among QHP issuers. A review of QHP issuer formularies in the 39 FFE and SBE–FP states for which we have data reveals that, while many QHPs cover all four MAT drugs, not all do. Specifically, for plan year 2018, 2,553 QHPs (95 percent) in these 39 FFE and SBE–FP states cover all four of these drugs; 105 QHPs (4 percent) cover three; and 25 QHPs (<1 percent) cover two. Given the effectiveness of MAT and the severity of the nationwide opioid Public Health Emergency, we encourage every health insurance plan to provide comprehensive coverage of MAT, even if the applicable EHB-benchmark plan does not require the inclusion of all four MAT drugs on a formulary. We encourage issuers to take every opportunity to address opioid use disorder, including increasing access to MAT and normalizing its use.¹²³

In addition, we have become aware that a MAT drug's inclusion on a formulary does not necessarily ensure coverage of that drug when administered for MAT. We are aware that some issuers utilize plan designs which exclude coverage of certain drugs

when used for MAT while the same drugs are covered for other medically necessary purposes, such as analgesia or alcohol use disorder. Under § 156.125, which implements the provision prohibiting discrimination, an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

We remind issuers that any indication of a reduction in the generosity of a benefit in some manner for subsets of individuals that is not based on clinically indicated, reasonable medical management practices is potentially discriminatory. As is the case for any EHB, issuers are expected to impose limitations and exclusions on the coverage of benefits to treat opioid use disorder, including the drugs used for MAT or any associated benefit such as counseling or drug screenings, based on clinical guidelines and medical evidence, and are expected to use reasonable medical management. If a plan excludes certain treatment of opioid use disorder, but covers the same treatment for other medically necessary purposes, the issuer must be able to justify such an exclusion with supporting documentation explaining how such a plan design is not discriminatory.

We note that a similar standard is imposed under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (section 2726 of the PHS Act).¹²⁴ Under regulations implementing the EHB requirements,¹²⁵ the requirements of MHPAEA are extended to issuers of non-grandfathered health insurance coverage in the individual and small group markets, both on and off the Exchange. Under HHS regulations at § 146.136 implementing MHPAEA, if a drug is offered under a plan for treatment of a medical condition but is excluded for MAT purposes, that is considered to be a nonquantitative treatment limitation.¹²⁶ A nonquantitative treatment limitation cannot be imposed on mental health or substance use disorder benefits in any classification¹²⁷

unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards or other factors used in applying the limitation to the mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than the processes, strategies, evidentiary standards and other factors used in applying the limitation to medical surgical benefits in the same classification. In other words, the issuer must demonstrate that, as written and in operation, the processes, strategies, evidentiary standards, and other factors it applied in deciding that the drug is covered for medical/surgical purposes, are comparable to those it used in deciding that the drug is not covered for MAT purposes, and that there are no limitations that apply only for mental health or substance use disorder benefits.¹²⁸

We also note that federal civil rights laws, such as title II of the Americans with Disabilities Act and section 504 of the Rehabilitation Act, prohibit discrimination against individuals who participate in or have completed substance use disorder treatment, including MAT.

e. Premium Adjustment Percentage (§ 156.130)

Section 1302(c)(4) of the PPACA directs the Secretary to determine an annual premium adjustment percentage, a measure of premium growth that is used to set the rate of increase for three parameters detailed in the PPACA: (1) The maximum annual limitation on cost sharing (defined at § 156.130(a)); (2) the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code (defined at § 155.605(d)(2)); and (3) the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code (see section 4980H(c)(5) of the Code). Section 1302(c)(4) of the PPACA and § 156.130(e) provide that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and the regulations provide that this percentage will be published in the annual HHS notice of benefit and payment parameters.

The 2015 Payment Notice (79 FR 13743) and 2015 Market Standards Rule

emergency care; and prescription drugs. 45 CFR 146.136(c)(2)(ii).

¹²⁸ See 45 CFR 146.136(c)(4)(iii), Ex. 10.

23. November 1, 2017. Available at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

¹²¹ There are four drugs currently used in MAT: Buprenorphine; naltrexone; buprenorphine in combination with naloxone; and methadone.

¹²² "Medication and Counseling Treatment". September 28, 2015. Available at <https://www.samhsa.gov/medication-assisted-treatment/treatment>.

¹²³ "For many people struggling with addiction, failing to offer MAT is like trying to treat an infection without antibiotics. . . . We know that there is sometimes stigma associated with MAT—especially with long term therapy. But someone on MAT, even one who requires long-term treatment, is not an addict. They need medicine to return to work; re-engage with their families; and regain the dignity that comes with being in control of their lives. These outcomes are literally the opposite of how we define addiction. Our fellow citizens who commit to treatment should not be treated as pariahs—they are role models." Azar, Alex. Plenary Address to National Governors Association, February 24, 2018. Available at <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-address-to-national-governors-association.html>.

¹²⁴ MHPAEA originally applied to large group health plans and large group health insurance coverage, and PPACA extended it to apply to individual health insurance coverage.

¹²⁵ 45 CFR 156.115(a)(3).

¹²⁶ For examples of nonquantitative treatment limitations, see 45 CFR 146.136(c)(4)(ii).

¹²⁷ Classifications under MHPAEA are as follows: Inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network;

(79 FR 30240) established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage for the 2015 benefit year and beyond. Beginning with the 2015 benefit year, the premium adjustment percentage was calculated based on the estimates and projections of average per enrollee employer-sponsored insurance premiums from the NHEA, which are calculated by the CMS Office of the Actuary. In the proposed 2015 Payment Notice, we proposed that the premium adjustment percentage be calculated based on the projections of average per enrollee private health insurance premiums. Based on comments received, we finalized the 2015 Payment Notice to instead use per enrollee employer-sponsored insurance premiums in the methodology for calculating the premium adjustment percentage. We chose employer-sponsored insurance premiums because they reflected trends in health care costs without being skewed by individual market premium fluctuations resulting from the early years of implementation of the PPACA market reforms. We adopted this methodology in subsequent Payment Notices for 2016 through 2019, but noted in the 2015 Payment Notice that we may propose to change our methodology after the initial years of implementation of the market reforms, once the premium trend is more stable.

We are proposing to use an alternative premium measure that captures increases in individual market premiums in addition to increases in employer-sponsored insurance premiums for purposes of calculating the premium adjustment percentage for the 2020 benefit year and beyond. The premium measure we propose to use to calculate the premium adjustment percentage for the 2020 benefit year and beyond is an adjusted private individual and group market health insurance premium measure, which is similar to NHEA's private health insurance premium measure. NHEA's private health insurance premium measure includes premiums for employer-sponsored insurance, "direct purchase insurance," which includes individual market health insurance purchased directly by consumers from health insurance issuers, both on and off the Exchanges, and Medigap insurance, and the medical portion of accident insurance ("property and casualty" insurance). The measure we propose to use is published by NHEA and includes NHEA estimates and projections of employer-sponsored insurance and direct purchase insurance premiums,

but would exclude premiums for Medigap and property and casualty insurance (we refer to the proposed measure as "private health insurance (excluding Medigap and property and casualty insurance)"). We are proposing to exclude Medigap and property and casualty insurance from the premium measure since these types of coverage are not considered primary medical coverage for individuals who elect to enroll. For example, Medigap coverage supplements the primary coverage obtained through Medicare by offering protection against certain out-of-pocket costs not covered by that program such as its associated co-payments and deductibles. We are proposing to use per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) so that the premium growth measure more closely reflects premium trends for all individuals primarily covered in the private health insurance market since 2013. Between 2014 and 2018, private individual health insurance market per enrollee premiums, specifically, premiums for coverage through the Exchanges, have grown faster than employer-sponsored insurance premiums. The majority of Exchange enrollees qualify to receive the premium tax credit, and federal premium tax credit expenditures have increased as Exchange premiums have increased. We anticipate that the proposed change to use per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) would make the premium index more closely reflect premium trends for individuals covered in the private health insurance market, and would additionally reduce federal premium tax credit expenditures, if the Department of the Treasury and the IRS adopt the proposed change, as explained later in this section. Specifically, to calculate the premium adjustment percentage for the 2020 benefit year, the measures for 2013 and 2019 would be calculated as private health insurance premiums minus premiums paid for Medigap insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees. These results would then be rounded to the nearest \$1 followed by a division of the 2019 figure by the 2013 figure rounded to 10 significant digits. The proposed premium measure would reflect cumulative, historic growth in premiums for private health insurance markets (excluding Medigap and

property and casualty insurance) from 2013 onwards.

As discussed in the 2015 Payment Notice, we considered four criteria when finalizing the premium adjustment percentage methodology for the 2015 benefit year: (1) Comprehensiveness—the premium adjustment percentage should be calculated based on the average per capita premium for health insurance coverage for the entire market, including the individual and group markets, and both fully insured and self-insured group health plans; (2) Availability—the data underlying the calculation should be available by the summer of the year that is prior to the calendar year so that the premium adjustment percentage can be published in the annual HHS notice of benefit and payment parameters in time for issuers to develop their plan designs; (3) Transparency—the methodology for estimating the average premium should be easily understandable and predictable; and (4) Accuracy—the methodology should have a record of accurately estimating average premiums. We continue to consider these criteria as we evaluate other sources of premium data that could be used in calculating the premium adjustment percentage.

Using the private health insurance premium measure data (excluding Medigap and property and casualty insurance) proposed above, we propose that the premium adjustment percentage for 2020 be the percentage (if any) by which the most recent NHEA projection of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2019 (\$6,468) exceeds the most recent NHEA estimate of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 (\$4,987).¹²⁹ Using this formula, the proposed premium adjustment percentage for 2020 is 1.2969721275 (\$6,468/\$4,987), which is an increase in private health insurance (excluding Medigap and property and casualty insurance) premiums of approximately 29.7

¹²⁹ The 2013 and 2019 premiums used for this calculation reflect the latest NHEA data. The series used in the determinations of the adjustment percentages can be found in Tables 1 and 17 on the CMS website, which can be accessed by clicking the "NHE Projections 2017–2026—Tables" link located in the Downloads section at the following address: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>. A detailed description of the NHE projection methodology is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf>.

percent over the period from 2013 to 2019.

We believe that our proposal to use per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance) in the premium adjustment percentage calculation could result in a faster premium growth rate for the foreseeable future than if we continued to use only employer-sponsored insurance premiums as in prior benefit years. We anticipate that this proposed change could have several impacts on the health insurance market. As explained above, the premium adjustment percentage is used to set the rate of increase for the maximum annual limitation on cost sharing, the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code. Accordingly, a premium adjustment percentage that reflects a faster premium growth rate would result in a higher maximum annual limitation on cost sharing, a higher required contribution percentage, and higher employer shared responsibility payment amounts than if the current premium adjustment percentage premium measure (employer-sponsored insurance only) were adopted for the 2020 benefit year.

Furthermore, to date the NHEA projections of per enrollee employer-sponsored insurance premiums have also been used by the Department of the Treasury and the IRS for determining the applicable percentage in section 36B(b)(3)(A) of the Code and the required contribution percentage in section 36B(c)(2)(C) of the Code.¹³⁰ The applicable percentage in section 36B(b)(3)(A) of the Code is used to determine the amount an individual must contribute to the cost of an Exchange QHP and thus, relates to the amount of the individual's premium tax credit. This is because, in general, an individual's premium tax credit is the lesser of (1) the premiums paid for the Exchange QHP, and (2) the excess of the premium for the benchmark plan over the contribution amount. The contribution amount is the product of the individual's household income and the applicable percentage.

The required contribution percentage in section 36B(c)(2)(C) of the Code is used to determine whether an offer of employer-sponsored insurance is considered affordable for an individual, which relates to eligibility for the premium tax credit because an

individual with an offer of affordable employer-sponsored insurance that provides minimum value is ineligible for the premium tax credit. Specifically, an offer of employer-sponsored insurance is considered affordable for an individual if the employee's required contribution for employer-sponsored insurance is less than or equal to the required contribution percentage (set at 9.5 percent in 2014) of the individual's household income.¹³¹

Section 36B(b)(3)(A)(ii) of the Code generally provides that the applicable percentages are to be adjusted after 2014 to reflect the excess of the rate of premium growth over the rate of income growth for the preceding year. Section 36B(c)(2)(C) of the Code provides that the required contribution percentage is to be adjusted after 2014 in the same manner as the applicable percentages are adjusted in section 36B(b)(3)(A)(ii) of the Code. As noted above, the Department of the Treasury and the IRS have issued guidance providing that the rate of premium growth for purposes of these section 36B provisions is based on per enrollee spending for employer-sponsored insurance as published in the NHEA.¹³² If we finalize a change to the premium measure used in the premium adjustment percentage for the 2020 benefit year, we expect the Department of the Treasury and the IRS to issue additional guidance to adopt the same premium measure for purposes of future indexing of the applicable percentage and required contribution percentage under section 36B of the Code.

We anticipate that a measure of premium growth that reflects a faster premium growth rate would increase the portion of the premium the consumer is responsible for paying and therefore would decrease the amount of premium tax credit for which consumers qualify under section 36B(b)(3)(A) of the Code. It also would increase the required contribution percentage under section 36B(c)(2)(C) of the Code, such that individuals with an offer of employer-sponsored insurance would be more likely to be ineligible for the premium tax credit. We recognize that federal outlays for the premium tax credit increased significantly in the 2018 benefit year, as many issuers increased silver plan premiums to offset the cost of providing cost-sharing reductions to eligible enrollees. The proposed change to the measure of premium growth, if also adopted by the

Department of the Treasury and the IRS for purposes of indexing the parameters under section 36B of the Code, would help to slow the increase in premium tax credit expenditures that results from this practice, thereby reducing taxpayer burden associated with premium tax credit expenditures. However, the proposed change could also contribute to a decline in Exchange enrollment among premium tax credit eligible consumers, and could ultimately result in net premium increases for enrollees that remain in the individual market, both on and off the Exchanges, as healthier enrollees elect not to purchase Exchange coverage.

Additionally, the Health Insurance Providers Fee established under section 9010 of the PPACA also takes the measure of premium growth used for the applicable percentage in section 36B(b)(3)(A)(ii) into consideration for purposes of calculating the fee for 2019 and beyond.¹³³ If the Department of the Treasury and the IRS adopt a faster premium growth rate, that would result in higher Health Insurance Providers Fees imposed on health insurance issuers that are required to pay the fee, over the long term. We anticipate that health insurance issuers subject to the Health Insurance Providers Fee may pass the fee on to consumers, thereby increasing premiums in the individual, small, and large group markets, although we anticipate the increases in premiums due to the increase in the Health Insurance Providers Fee will be marginal.

We considered using Exchange premiums as the measure for premium growth instead of the proposed private health insurance (excluding Medigap and property and casualty insurance) premium measure. Using Exchange premiums would result in a faster premium growth rate than the proposed measure and the employer-sponsored insurance measure used in the premium adjustment percentage calculation for the 2015 through 2019 benefit years. As such, we anticipate that a premium growth measure based on Exchange premiums would result in even larger increases in the maximum annual limitation on cost sharing, required contribution percentage, and employer shared responsibility payment amounts, and, if adopted by the Department of the Treasury and the IRS, would result in even larger reductions in premium tax credit expenditures. However, a

¹³¹ See also IRS Notice 2015-87, Q&A 12 for discussion of the adjustment of the required contribution percentage as applied for certain purposes under sections 4980H and 6056 of the Code.

¹³² See IRS Rev. Proc. 2014-37.

¹³³ See PPACA section 9010(e)(2). However, pursuant to section 4003 of Public Law 115-120, Division D—Suspension of Certain Health-Related Taxes, enacted on January 22, 2018, the collection of the Health Insurance Providers Fee is suspended for the 2019 calendar year.

¹³⁰ IRS Rev. Proc. 14-37.

significant drawback with using Exchange premiums is that the Exchanges did not exist in 2013, and therefore Exchange premiums are not available for 2013. NHEA does not currently publish projections of Exchange premiums separate from the estimates and projections that they include within the direct purchase premium measure (a projection would be needed for the 2019 premium amount).

Based on the proposed 2020 premium adjustment percentage, we propose the following cost-sharing parameters for benefit year 2020.

Maximum Annual Limitation on Cost Sharing for Plan Year 2020

Under § 156.130(a)(2), for the 2020 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2020. For other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of \$50. Using the premium adjustment percentage of 1.2969721275 for 2020 as proposed above, and the 2014 maximum annual limitation on cost sharing of \$6,350 for self-only coverage, which was published by the IRS on May 2, 2013,¹³⁴ we propose that the 2020 maximum annual limitation on cost sharing would be \$8,200 for self-only coverage and \$16,400 for other than self-only coverage. This represents an approximately 3.8 percent increase above the 2019 parameters of \$7,900 for self-only coverage and \$15,800 for other than self-only coverage. We seek comment on this proposal.

f. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

Sections 1402(a) through (c) of the PPACA direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver-level QHP. In the 2014 Payment Notice, we established standards related to the provision of these cost-sharing reductions. Specifically, in part 156, subpart E, we specified that QHP issuers must provide cost-sharing reductions by developing plan variations, which are separate cost-sharing structures for each eligibility category that change how the cost sharing required under the QHP is to be shared between the enrollee and the federal government. At § 156.420(a), we detailed the structure of these plan

variations and specified that QHP issuers must ensure that each silver-plan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the PPACA, section 1402(c)(1)(B)(ii) states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AV of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee). Accordingly, we propose to continue to use the method we established in the 2014 Payment Notice for determining the appropriate reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations.

As we proposed above, the 2020 maximum annual limitation on cost sharing would be \$8,200 for self-only coverage and \$16,400 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. Below, we describe our analysis for the 2020 plan year and our proposed results.

Consistent with our analysis in the Payment Notices for 2014 through 2019, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the PPACA to the proposed estimated 2020 maximum annual limitation on cost sharing for self-only coverage (\$8,200). The test plan designs are based on data collected for 2019 plan year QHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchanges. For 2020, the test silver level QHPs included a PPO with typical cost-sharing structure (\$8,200 annual limitation on cost sharing, \$2,575 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing (\$5,250 annual limitation on cost sharing, \$3,500 deductible, and 20 percent in-network coinsurance rate); and an HMO (\$8,200 annual limitation on cost sharing, \$4,300 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the

deductible or coinsurance: \$500 inpatient stay per day, \$500 emergency department visit, \$25 primary care office visit, and \$55 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into the proposed 2020 AV Calculator and observed how the reductions in the maximum annual limitation on cost sharing specified in the PPACA affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 100 and 150 percent of FPL ($\frac{2}{3}$ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of FPL ($\frac{2}{3}$ reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively). In contrast, the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 200 and 250 percent of FPL ($\frac{1}{2}$ reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we propose that the maximum annual limitation on cost sharing for enrollees with a household income between 200 and 250 percent of FPL be reduced by approximately $\frac{1}{5}$, rather than $\frac{1}{2}$, consistent with the approach taken for benefit years 2017 through 2019. We further propose that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of FPL be reduced by approximately $\frac{2}{3}$, as specified in the statute, and as shown in Table 9. These proposed reductions in the maximum annual limitation on cost sharing should adequately account for unique plan designs that may not be captured by our three model QHPs. We also note that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in the aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level.

In prior years we found, and we continue to find, that for individuals with household incomes of 250 to 400 percent of FPL, without any change in other forms of cost sharing, any reduction in the maximum annual limitation on cost sharing will cause an

¹³⁴ See <http://www.irs.gov/pub/irs-drop/rp-13-25.pdf>.

increase in AV that exceeds the maximum 70 percent level in the statute. As a result, we do not propose to reduce the maximum annual limitation on cost sharing for individuals with household incomes between 250 and 400 percent of FPL.

We seek comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing for 2020.

We note that for 2020, as described in § 156.135(d), states are permitted to submit for approval by HHS state-

specific datasets for use as the standard population to calculate AV. No state submitted a dataset by the September 1, 2018 deadline.

TABLE 9—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2020

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2020	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2020
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(i) (100–150 percent of FPL)	\$2,700	\$5,400
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(ii) (151–200 percent of FPL)	2,700	5,400
Individuals eligible for cost-sharing reductions under § 155.305(g)(2)(iii) (201–250 percent of FPL)	6,550	13,100

g. Application to Cost-Sharing Requirements and Annual and Lifetime Dollar Limitations (§ 156.130)

We are proposing several policy changes to cost-sharing requirements, including a policy change as to what is included as EHB, which affects the annual out-of-pocket limitation under PHS Act section 2707(b) and the annual and lifetime dollar limit prohibition under PHS Act section 2711. Although large group market coverage and self-insured group health plans are not required to cover all EHB, non-grandfathered group health plans and health insurance issuers are subject to PHS Act section 2707(b), and all group health plans and group health insurance issuers are subject to PHS Act section 2711, which are incorporated by reference in the Employee Retirement Income Security Act of 1974 (ERISA) and the Code.¹³⁵ To comply with those sections, such plans and issuers must choose a definition of EHB to determine which benefits are subject to the annual out-of-pocket limitation and the prohibition on lifetime and annual dollar limits.¹³⁶ Therefore, these

proposals are relevant to, and would apply to, all health coverage and plans.

i. Cost-Sharing Requirements for Generic Drugs

In 2014, the Departments of Labor, HHS, and the Treasury¹³⁷ (the tri-departments) released an FAQ on the treatment by large group market health insurance issuers and self-insured group health plans, with regard to the annual out-of-pocket limitation, of an individual's out-of-pocket costs for a brand drug when a generic equivalent is available and medically appropriate. Because large group market health insurance issuers and self-insured group health plans are not required to offer EHB, the FAQ states that such plans may include only generic drugs, if medically appropriate (as determined by the individual's personal physician) and available as EHB, while providing a separate option (not as part of EHB) of selecting a brand drug at a higher cost-sharing amount, as non-EHB. Thus, such plans could choose not to count toward the annual limit on cost sharing some or all of the amounts paid toward the brand drugs that are not EHB, if the participant or beneficiary selects a brand name prescription drug in circumstances in which a generic was available and medically appropriate (as determined by the individual's personal physician).¹³⁸

The FAQ also states that for non-grandfathered health plans in the individual and small group markets that must provide coverage of EHB, additional requirements apply.¹³⁹ This reflects the implementation of the EHB requirements as implemented in the Patient Protection and Affordable Care Act (PPACA); Standards Related to Essential Health Benefits, Actuarial Value and Accreditation; Final Rule (EHB Final Rule),¹⁴⁰ in which we stated that plans are permitted to go beyond the number of drugs offered by the EHB-benchmark plan without exceeding EHB. We further clarified in the 2016 Payment Notice that, if the plan is covering drugs beyond the number of drugs covered by the EHB-benchmark plan, all of these drugs are EHB and cost sharing paid for the drugs must count toward the annual limitation on cost sharing.¹⁴¹

Given the increase in the cost of prescription drugs, and particularly brand drugs, HHS believes additional flexibility is needed for health plans in the individual and small group markets that must provide coverage of the EHB to encourage consumers to use more cost effective generic drugs. Therefore, we propose, subject to applicable state law, to allow a plan that covers both a brand prescription drug and its generic equivalent, for plan years beginning on or after January 1, 2020, to consider the brand drug to not be EHB, if the generic drug is available and medically appropriate for the enrollee, unless

¹³⁵ Sections 2707(b) and 2711 of the PHS Act apply the annual cost-sharing limitation on EHBs and the prohibition on annual dollar limits on EHBs to non-grandfathered non-federal governmental group health plans of all sizes, and by implication, to large group health insurance issuers through which such plan provide coverage. Additionally, section 715 of ERISA and section 9815 of the Code incorporates those provisions by reference, applying them to non-grandfathered privately sponsored group health plans and their health insurance issuers in the small and large group markets.

¹³⁶ Generally, for this purpose, a group health plan or health insurance issuer that is not required to provide EHB must define such benefits in a manner that is consistent with—(1) one of the EHB-benchmark plans applicable in a state under 45 CFR 156.110, or (2) one of the three Federal Employees Health Benefits Program plan options. 45 CFR 147.126(c).

¹³⁷ FAQs About Affordable Care Act Implementation (Part XIX). May 2, 2014. Available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html. This FAQ remains in effect for large group market and self-insured group health plans.

¹³⁸ In determining whether a generic is medically appropriate, the FAQ provides that a plan may use a reasonable exception process. For example, the plan may defer to the recommendation of an individual's personal physician, or it may offer an exceptions process meeting the requirements of 45 CFR 156.122(c).

¹³⁹ For example, these plans have to meet the EHB drug count standard at § 156.122(a) that sets a minimum threshold for drug coverage and while the drug count standard is based on chemically distinct drugs, these plans have to consider other factors in establishing their prescription drug benefit.

¹⁴⁰ 78 FR 12834, 12845 (February 25, 2013).

¹⁴¹ 80 FR 10817.

coverage of the brand drug is determined to be required under an exception process at § 156.122(c).

Under such circumstances, if an enrollee purchases the brand drug when the generic equivalent was available and medically appropriate, we propose that the issuer would be permitted to not count the difference in cost sharing between that which is paid for the brand drug and that which would be paid for the generic equivalent drug toward the annual limitation on cost sharing under § 156.130, but would still be required to attribute the cost sharing that would have been paid for the generic equivalent toward the annual limitation on cost sharing under § 156.130. This would maintain a balance between incentivizing the use of lower-cost drugs and the consumer protection provided by the annual limitation on cost sharing.

We further propose that for a plan to do so, the plan must have an exception process in place in accordance with § 156.122(c) for the enrollee to request coverage of the brand drug.

If finalized, this interpretation would permit all group health plans and group health insurance issuers to impose lifetime and annual dollar limits on such brand drugs because they would no longer be considered EHB subject to the prohibition on such limits.

HHS is also considering an alternate proposal, under which an issuer would be permitted to except the entire amount paid by a patient for a brand drug for which there is a medically appropriate generic alternative from the annual limitation on cost sharing at § 156.130. Because this alternate proposal also relies on an interpretation of what is considered EHB, the alternate proposal would also apply to non-grandfathered group health plans and health insurance issuers subject to the annual limit on cost-sharing provision under PHS Act 2707(b), and in ERISA section 715 and Code section 9815.

Under the alternate proposal, for example, if an enrollee with a 10 percent coinsurance obligation is selecting between a brand drug for which the allowable charge is \$100 and an available and medically appropriate generic equivalent for which the allowable charge is \$60, if the enrollee selects the generic equivalent, the enrollee would pay \$6 in coinsurance (10 percent of the \$60 allowable charge) and the issuer would attribute that \$6 to the annual limitation on cost sharing. If the enrollee selects the brand drug, the enrollee would pay \$10 in coinsurance (10 percent of \$100), but the issuer could attribute \$6 to the annual limitation on cost sharing under the first proposal (due to the enrollee selecting a

brand name drug when a generic equivalent is available and medically appropriate) or \$0 under the alternate proposal to the annual limitation on cost sharing.

We propose that these changes to the annual limitations on cost sharing would be effective starting with the 2020 plan year. We solicit comments on these alternatives, both of which we propose to apply to group health plans, group health insurance coverage, and individual market coverage, regardless of whether they are required to cover EHBs.

An issuer taking advantage of this proposed flexibility would be excluding the brand drug from coverage as EHB. Therefore, the issuer also could impose annual or lifetime dollar limits on coverage of the brand drug under those circumstances. Additionally, PTC (and APTC) could not be applied to any portion of the premium attributable to coverage of brand name drugs not covered as EHB, so issuers of QHPs would be required to calculate that portion of QHPs' premiums and report it to the applicable Exchange.

We also solicit comments on any limitation on group health plans' and health insurance issuers' information technology systems being able to accumulate the cost sharing consistent with this policy, whether this proposed policy should be subject to or preempt any state law regarding the application of cost sharing between the generic and branded version of a drug that would prevent the application of this proposed policy, and whether an issuer not attributing cost-sharing to the annual limitation on cost sharing under this approach should be considered an adverse coverage determination and subject to the coverage appeals processes under § 147.136.

Finally, we seek comment regarding whether we should *require*, instead of permit, issuers to exclude brand drugs from being EHB if the generic drug is available and medically appropriate for the enrollee, unless coverage of the brand drug is determined to be required under the exception process under 156.122(c), and to exclude the cost sharing for the brand name drug from accumulating toward the annual limitation on cost sharing according to one of the alternatives proposed above.

ii. Cost-Sharing Requirements and Drug Manufacturers' Coupons

Drug manufacturers often offer coupons to patients to reduce patient out-of-pocket costs. Drug manufacturers may offer these coupons for various reasons: To compete with another brand name drug in the same therapeutic

class, to compete with a generic equivalent when released, or to assist consumers whose drug costs would otherwise be extremely high due to a rare or costly condition.¹⁴² Some states prohibit the use of such coupons if a generic alternative is available.¹⁴³

We recognize that copayment support may help beneficiaries by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients. However, the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices which can distort the market and the true costs of drugs. Such coupons can add significant long-term costs to the health care system that may outweigh the short-term benefits of allowing the coupons, and counter-balance issuers' efforts to point enrollees to more cost effective drugs.

The Administration has identified high and rising out-of-pocket costs for prescription drugs, among other issues, as a challenge to consumers. In some cases, manufacturer coupons may be increasing overall drug costs and can lead to unnecessary spending by issuers, which is passed on to all patients in the form of increased premiums and reduced coverage of other potentially useful health care interventions. While the PPACA does not speak directly to the accounting and use of drug manufacturer coupons to the annual limitation on cost sharing, we believe that the overall intent of the law was to establish annual limitations on cost sharing that reflect the actual costs that are paid by the enrollee. The proliferation of drug coupons supports higher cost brand drugs when generic alternatives are available which in turn supports higher drug prices and increased costs to all Americans and for other federal health programs.

For these reasons, at new § 156.130(h)(2), we propose, for plan years beginning on or after January 1, 2020, notwithstanding any other provision of the annual limitation on cost sharing regulation, that amounts paid toward cost sharing using any form

¹⁴² Van Nuys, K., Joyce, G., Ribero, R., & Goldman, D.P. (2018). A Perspective on Prescription Drug Copayment Coupons. Los Angeles, CA: Leonard D. Schaeffer Center for Health Policy & Economics.

¹⁴³ For example, see, <https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXIII/Chapter175H/Section3>.

of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent are not required to be counted toward the annual limitation on cost sharing. Not counting such amounts toward the annual limitation on cost sharing would promote: (1) Prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs and (2) price competition in the pharmaceutical market.

We seek comment on this proposal and whether states should be able to decide how coupons are treated. Additionally, we seek comment on whether it would be difficult for issuers to carve out direct support offered by drug manufacturers from their calculation of enrollees' payments toward their annual limitation on cost sharing, and to carve out exceptions (for when a generic equivalent is not available, for example), when cost sharing paid by direct support offered by drug manufacturers would be counted toward the annual limitation on cost sharing, including whether information technology systems could be easily updated for this purpose. We also seek comment on issuers' ability to differentiate between drug manufacturer coupons and other drug coupons, whether their information technology systems would need modifications to make such differentiation, what a reasonable implementation date would be if implementation barriers exist, and how drug discount programs (as opposed to coupons) should be treated under this proposal. Finally, we seek comment regarding whether this policy should be limited to QHPs only.

4. Segregation of Funds for Abortion Services (§ 156.280)

We believe that consumers are best served by the Exchanges when they have a choice of QHPs, understand the benefits their coverage provides, and can select a QHP that best meets their needs. To that end, the Exchanges were established such that issuers may offer consumers coverage at different metal levels, and with different benefits, cost sharing, and networks, among other things. In the FFEs, we have taken steps to improve transparency regarding QHP offerings and make it easier for consumers to select plans that they believe are best suited to their needs and preferences, such as providing information to identify QHPs that offer non-Hyde abortion services. State Exchanges have taken similar steps. For example, Exchanges display different

plan attributes to consumers to foster the decision-making process, and allow consumers to view plan offerings by selecting filters that show plans with their desired plan characteristics. In addition, SBC requirements help ensure that consumers have access to easy-to-understand information about coverage. However, in spite of these steps, there may be instances where a consumer prefers to enroll in a QHP that does not offer coverage for non-Hyde abortion services, but is unable to do so if such a plan is not offered in his or her service area.

In particular, we are concerned that there are consumers who wish to enroll in a QHP but who may object to having non-Hyde abortion benefits included in their health insurance coverage based on religious or moral (collectively, conscience) objections. To the extent that potential enrollees will not enroll in, or are discouraged from enrolling in QHPs because all plans available in their service area cover non-Hyde abortion, we want to ensure that they are offered plan options that do not cover such services, to encourage QHP enrollment. Therefore, we propose at § 156.280(c)(3) that, beginning with plan year 2020, if a QHP issuer provides coverage of non-Hyde abortion services in one or more QHPs, the QHP issuer must also offer at least one "mirror QHP" that omits coverage of non-Hyde abortion services throughout each service area in which it offers QHP coverage through the Exchange, to the extent permissible under state law. We propose that a "mirror QHP" provide identical benefit coverage to one of the QHPs with non-Hyde abortion coverage, with the exception of the inclusion of the coverage of non-Hyde abortion services. Under this proposal, the QHP issuer would only be required to offer at least one "mirror QHP" throughout each service area that the QHP issuer offers plans covering non-Hyde abortion coverage, even if the issuer has multiple plans that offer non-Hyde abortion services in a single service area. Under this proposal, the QHP issuer would determine at which metal level the mirror plan is offered. We seek comment on the extent to which allowing QHP issuers to determine at which metal level the mirror plan is offered may inhibit access to these plans.

This proposal implements our authority in section 1321 of the PPACA to impose, through rulemaking, such "requirements" pertaining to PPACA provisions not codified in the Public Health Service Act "as the Secretary determines appropriate" to establish standards for certification of QHPs,

consistent with section 1311(c)(1) of the PPACA. The proposed requirement at § 156.280(c)(3) to offer a mirror QHP would help ensure that individuals who would otherwise purchase a QHP, but could not avail themselves of such plans because of the policy's coverage of non-Hyde abortion services, could get the same plan benefits through the Exchange under a policy that does not include the coverage to which they object.

We recognize the argument that the requirement to offer a mirror QHP that we are proposing at § 156.280(c)(3) may be inconsistent with a QHP issuer's right under section 1303(b)(1)(A)(ii) of the PPACA to decide whether or not to provide coverage of non-Hyde abortions services as part of its essential health benefits, if not prohibited from doing so under state law.¹⁴⁴ However, we do not believe that such a requirement is inconsistent with section 1303(b)(1)(A)(ii) of the PPACA. We interpret that provision as giving issuers offering QHPs in states that do not prohibit coverage of non-Hyde abortion services the right to decide whether or not to provide coverage of such abortion services. Specifically, we interpret section 1303(b)(1)(A)(ii) of the PPACA as intended to ensure, where applicable, that the decision on whether or not to provide coverage of non-Hyde abortion services is up to the issuer.¹⁴⁵ That is, section 1303(b)(1)(A)(ii) of the PPACA would preclude the federal government from prohibiting QHP issuers from offering QHPs that offer abortion coverage, including non-Hyde abortion coverage; it does not preclude requiring a QHP issuer that offers non-Hyde abortion services in its QHPs to also offer at least one mirror QHP in each service area that does not cover non-Hyde abortion services.

This issuer's right to decide whether or not to offer coverage of non-Hyde abortion services in a QHP need not necessarily be read to give issuers a right under federal law to provide such coverage under every single QHP they offer, where not prohibited by the state

¹⁴⁴ Section 1303(b)(1)(A)(ii) of the PPACA provides ("[n]otwithstanding any other provision of [title I of the PPACA] (or any amendment made by this title)", that if a state has not prohibited abortion coverage on the Exchange, "the issuer of a qualified health plan shall determine whether or not the plan provides coverage" of abortion services as part of the EHB covered under the QHP.

¹⁴⁵ Based on the Dictionary Act at 1 U.S. Code 1, which enables the use of plural in place of singular and vice versa unless context indicates otherwise, the common usage of issuer in section 1303(b)(1)(A)(ii) of PPACA may be read to refer to the issuer's right to decide whether or not to offer abortion coverage at all for that plan year rather than the right to make such a decision for each of the issuer's plans for that plan year.

from doing so. Under our proposed interpretation at § 156.280(c)(3), as long as the state permits the QHP issuer to decide whether or not to provide coverage of non-Hyde abortion services under a QHP and does not affirmatively require the QHP issuers in the state to cover such services in all plans, section 1303(b)(1)(A)(ii) of the PPACA is satisfied, and the issuer's rights under section 1303(b)(1)(A)(ii) of the PPACA would not be undermined by the proposed requirement that issuers providing coverage of non-Hyde abortion services under a QHP also offer a QHP with identical coverage, with the exception of the inclusion of the coverage of non-Hyde abortion services.

We also seek comment on ways that Exchanges, and *HealthCare.gov* in particular, can differentiate between the QHP that covers non-Hyde abortions and the QHP that does not cover non-Hyde abortions. We realize that but for the premium and benefit description, the QHPs would otherwise appear identical, and are concerned that consumers who do not carefully study their plan options may be confused by the premium differential. Similarly, we seek comment on the extent to which QHP issuers participating in direct enrollment under § 156.1230 and agents and brokers utilizing an internet website in accordance with § 155.220(c)(3)(i) should be required to adhere to any standards established for Exchanges in terms of differential display of these two types of QHPs.

Given the proposed changes to this section, we are further proposing to rename this section "Rules relating to coverage of abortion services and segregation of premiums for such services." to better reflect its contents.

We seek comment on this proposal.

5. Quality Standards (§§ 156.1120, 156.1125, 156.1130)

Regulatory reform and reducing regulatory burden are high priorities for us. To lower health care costs, enhance patient care, and reduce the regulatory burden on the health care industry, including for health plan issuers and the providers who deliver services through their plans, in October 2017, we launched the Meaningful Measures Initiative.¹⁴⁶ This initiative is one component of our agency-wide Patients Over Paperwork Initiative.¹⁴⁷

The Meaningful Measures Framework is a strategic tool for putting patients over paperwork by reducing measure reporting burden, aligning with the national health care priorities, and fostering operational efficiencies that include decreasing data collection and reporting burden while focusing on quality measurement aligned with meaningful outcomes.

By including Meaningful Measures in our quality reporting and quality improvement programs such as the Quality Rating System, QHP Enrollee Experience Survey and the Quality Improvement Strategy, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We encourage QHP issuers to use performance measures aligned with the Meaningful Measures Initiative in fulfilling their certification requirement to implement a Quality Improvement Strategy that provides increased reimbursement or other market-based incentives for improving health outcomes of plan enrollees.

In addition, we will continue to assess quality measures in our programs including the Quality Rating System and the QHP Enrollee Experience Survey, to ensure that we are using a parsimonious set of the most meaningful measures for patients, clinicians, and health plans in those quality programs. If we propose any changes or removal of measures, we will include those for public comment in the Annual Call Letter for the QRS and QHP Enrollee Survey,¹⁴⁸ as well as address potential changes to information collection requirements to comply with the Paperwork Reduction Act.

6. Direct Enrollment With the QHP Issuer in a Manner Considered To Be Through the Exchange (§ 156.1230)

As previously described in the preamble to §§ 155.220, 155.221, and 155.415 we are proposing significant changes to §§ 155.221 and 155.415 to streamline and consolidate the requirements applicable to all direct

enrollment entities—both QHP issuers and web-brokers. To reflect these changes, we propose conforming changes in § 156.1230(a)(2) and (b). We propose to amend § 156.1230(b) to add a new paragraph (b)(1) that would require issuers participating in direct enrollment to comply with the applicable requirements in § 155.221. We also propose to delete and reserve paragraph (a)(2) of § 156.1230 to reduce redundancies in light of the proposed changes to § 155.415 that are described earlier in this rulemaking. For a more thorough discussion of these proposed changes, please see the preamble to §§ 155.220, 155.221, and 155.415.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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 OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA 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.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.¹⁴⁹ Table 10 in this proposed rule presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical

¹⁴⁶ "Meaningful Measures Hub." May 5, 2018. Available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html>.

¹⁴⁷ Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on

October 30, 2017. Available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html>.

¹⁴⁸ Final 2018 Call Letter for the QRS and QHP Enrollee Survey. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/2018-QRS-Call-Letter_July2018.pdf.

¹⁴⁹ See May 2017 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at https://www.bls.gov/oes/current/oes_nat.htm.

alternative, and we believe that doubling the hourly wage to estimate

total cost is a reasonably accurate estimation method.

TABLE 10—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES

Occupation title	Occupational code	Mean hourly wage (\$/hr.)	Fringe benefits and overhead (\$/hr.)	Adjusted hourly wage (\$/hr.)
Information and Record Clerks	43–4199	\$19.56	\$19.56	\$39.12
Computer Programmer	15–1131	42.08	42.08	84.16
Medical Records and Health Information Technician	29–2071	26.76	26.76	53.52
Compliance officer	13–1041	34.39	34.39	68.78
Operations manager	11–1021	59.35	59.35	118.70
All Occupations	00–0000	24.34	24.34	48.68

B. ICRs Regarding Guaranteed Renewability of Coverage (§§ 146.152, 147.106, 148.122, 156.122)

In an effort to optimize the use of new generic drugs as they become available, we proposed to allow issuers, beginning with plan years on or after January 1, 2020, to update their prescription drug formularies by allowing certain mid-year formulary changes, subject to applicable state law.

We propose that a health insurance issuer that makes one of the following mid-year drug formulary changes would be required to send a written notice to enrollees 60 days prior to implementing any of the following drug formulary changes:

- Adding a generic equivalent drug to the formulary, while removing the brand name drug from the formulary; or
- Adding a generic equivalent to a formulary and moving the equivalent brand name drug to a different cost-sharing tier.

Such changes would not be permitted to exceed the scope of what would otherwise be a uniform modification, and enrollees would retain the option to request coverage for a brand name drug that was removed from the formulary through the applicable coverage appeal process under § 147.136 or the drug exception request process under § 156.122(c).

Based on the 2016 Medical Loss Ratio (MLR) totals, there are 520 health insurance issuers with estimated 75.6 million enrollees. Given the approval trends from 2016 through 2018, we also estimate that the Food and Drug Administration approves an average of 76 first time generic drug applications per calendar year, allowing a first time generic equivalent of a brand drug to be manufactured.¹⁵⁰ However, not all of

these drugs are suitable for a drug formulary; some are only administered in a clinical setting, and others may be approved for over-the counter (OTC) use. We also considered that not all issuers will opt to make mid-year formulary changes. In reviewing the recent first time FDA generic equivalent approvals for 2018, 60 percent, or 37 generic equivalent drugs are available by prescription and could potentially be found on an issuers' formulary, resulting in a mid-year formulary change. If finalized as proposed, all enrollees would receive a notice regarding the mid-year formulary change. Finally, we estimate that 62 percent of notices will be sent by mail and the remaining electronically. The cost to print and send the notice would include \$0.05 per 1-page and \$0.50 per notice to mail. The total cost of sending notices by mail would be approximately \$15,481,400.

Issuers would have two options to make formulary changes, therefore we have provided two notice cost estimates for removing a brand drug from the formulary and for changing the cost-sharing tier for a brand drug.

Notice of Change: Removal of a Brand Drug From the Formulary

A health insurance issuer would be required to provide a written notice 60 days in advance. This notice would be required to identify the name of the brand drug that is the subject of the change, disclose whether the brand drug will be removed from the formulary or placed on a different cost-sharing tier, provide the name of the generic equivalent that will be made available, specify the date the changes will become effective, and state that under the appeals processes outlined in § 147.136 or the exceptions processes outlined in § 156.122(c), enrollees and

dependents may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan. Issuers also would be required to provide enrollees the option to request coverage for a brand drug that was removed from the formulary through the applicable coverage appeal process under § 147.136 or the drug exception request process under § 156.122(c). Therefore, we estimate that a "Notice of Change: Removal of a brand drug from the formulary," would require issuers 10 hours of clerical labor (at a cost of \$39.12 per hour) to prepare the custom notice using an existing standard notice or a standard notice provided by the issuer's state. The cost to print and send the notice would include \$0.05 per page and \$0.50 to mail. It would take an estimated 2 hour for a senior manager (at a cost of \$118.70 per hour) to review the notice template. We also estimate that it would take a computer programmer 10 hours (at a cost \$84.16 per hour) to write and test a program to automate the electronic notices. The total annual burden for each issuer to prepare the template would be 22 hours with an equivalent cost of approximately \$1,470. For all 520 health insurance issuers, the total annual burden would be 11,440 hours with an equivalent cost of approximately \$764,504. We assume that approximately half of the notices sent would be of this type, with a mailing cost of approximately \$7,740,700. The total annual cost for all issuers would be approximately \$8,505,204.

Notice of Change: Change to Cost-Sharing Tier for a Brand Drug

A health insurance issuer would provide the notice 60-days prior to adding a generic equivalent to a formulary, and moving the equivalent brand name drug to a different cost-sharing tier. Therefore, we estimate that a "Notice of Change: *Change to cost-sharing tier for a brand drug,*" would require 6 hours of clerical labor (at a

¹⁵⁰ See ANDA (Generic) Drug Approval Reports-2018. Available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/default.htm>. See also ANDA (Generic Drug Approval Reports Previous Years—

2016–17. Available at <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ucm050527.htm>.

cost of \$39.12 per hour) to prepare the custom notice using an existing standard notice or a standard notice provided by the issuer's state. The cost to print and send the notice would include \$0.05 per 1-page and \$0.50 per notice to mail. It would take an estimated 2 hours for a senior manager (at a cost of \$118.70 per hour) to review the notice template. We also estimate that it would take a computer programmer 10 hours (at a cost \$84.16 per hour) to write and test a program to automate the electronic notices. The total annual burden for each issuer to prepare the template would be 18 hours with an equivalent cost of approximately \$1,314. For all 520 health insurance issuers, the total annual burden would be 9,360 hours with an equivalent cost of approximately \$683,134. We assume that approximately half of the notices sent would be of this type, with a mailing

cost of approximately \$7,740,700. The total annual cost for all issuers would be approximately \$8,423,834.

As a subset of this notice requirement, at § 156.122(d)(3) we propose that QHP issuers in the FFEs would be required to notify HHS annually in an HHS-specified format of any mid-year formulary changes made in the prior plan year consistent with the policy proposed at § 147.106(e) that would allow an issuer to make mid-year drug formulary changes. QHP issuers in the FFEs would be required to report the name of the drug being removed from the formulary, dosage, name of the generic equivalent, the Rx Norm Concept Unique Identifier (RxCUI) associated with the brand and generic drug, if the brand drug was moved to a higher cost sharing tier or removed from the formulary. Issuers would be required to submit the formulary changes in a template as specified by

HHS. We estimate 66 QHP issuers (not including SADPs, but encompassing both individual and SHOP markets) will offer QHPs in an FFE and thus be subject to this requirement. The estimate of 66 is based on the number of issuers whose QHP issuers in an FFE, that appeared on *HealthCare.gov* in the 2019 plan year.

We estimate that it will take 42 hours per year for a QHP issuer in an FFE to meet this reporting requirement, which will occur annually. On average, we estimate that it will take an Information and Records Clerk 36 hours (at \$39.12 an hour), and a Senior Manager 6 hours (at \$118.70 an hour) to fulfill these requirements. The total estimated annual burden is 42 hours with an equivalent cost of approximately \$2,121 per reporting entity. The aggregate annual burden for all issuers would be 2,772 hours with an equivalent cost of approximately \$139,954.

TABLE 11—ESTIMATED ANNUALIZED BURDEN FOR NOTICES OF CHANGE FOR ALL HEALTH PLANS

Respondent	Type of notice	Number of respondents	Number of notices per respondent	Burden per notice (hours)	Cost per notice	Total burden for all respondents	Total labor cost for all respondents	Total cost (including mailing costs) for all respondents
Health Insurance Issuer.	Notice of Change: Removal of a brand drug from the formulary.	520	1	22	\$1470.20	11,444	\$764,504.00	\$8,505,204
Health Insurance Issuer.	Notice of Change: Change to Cost-sharing tier for a brand drug.	520	1	18	1313.72	9,360	683,134.40	8,423,834
Total	520	20,804	1,447,638.40

TABLE 12—ESTIMATED ANNUALIZED BURDEN FOR MID-YEAR FORMULARY CHANGE REPORTING TO QHP FFE ISSUERS

Labor category	Number of employees	Hourly labor costs (hourly rate + 35% fringe benefits)	Burden hours	Total burden costs	Total burden cost (per year)
Information and Records Clerk	1	\$39.12	36	\$1,408.32
Senior Manager	1	118.70	6	712.20
Total per Issuer	42	2,120.52
Total for the 66 QHP FFE Issuers	\$139,954.32

C. ICRs Regarding Varying the Risk Adjustment Initial Validation Audit Sample Size (§ 153.630(b))

The current enrollee sample size selected for the risk adjustment initial validation audit is 200 enrollees for each issuer's HIOS ID based on sample size precision analyses using data from the Medicare Advantage risk adjustment program.

Beginning with the 2019 benefit year of risk adjustment data validation,¹⁵¹ we propose to vary the initial validation

audit sample size, and one proposed approach would vary sample size based on issuer characteristics, such as issuer size, HCC failure rates, and sample precision. Larger initial validation audit samples could be required under our proposed approach; however, we believe that any increased burden would be outweighed by the increased precision of the risk adjustment data validation results which are used to adjust risk scores and associated risk adjustment transfers.

The first proposed approach we are considering would recalculate adjusted sample sizes above the current baseline

sample size of 200 only for larger and smaller issuers who are more than 1.644 standard deviations away from the mean for any HCC failure rate group.¹⁵² This targeted sampling adjustment would ensure that all issuers outside or just inside of the HCC failure rate outlier threshold (1.96 standard deviations)

¹⁵² As detailed in the above preamble, under this proposed approach, the sample size for very small issuers (those with below 3,000 enrollees calculated statewide based on the benefit year being validated) outside of 1.644 standard deviations from the mean of any HCC failure rate group, as well for issuers with HCC failure rates within 1.644 standard deviations of the mean for all HCC failure rate groups, would remain at 200 enrollees.

¹⁵¹ Activities related to the 2019 benefit year risk adjustment data validation generally begin in the second quarter of the 2020 calendar year.

receive sample sizes that better meet our targeted precision, that issuers receiving error rates are in fact outliers, and that issuers that did not receive an error rate, but had higher than average HCC failure rates were not false negatives due to low precision in their sample. Issuers in this subset whose sample size does not meet the targeted precision would have their initial validation audit sample size adjusted to more closely achieve the targeted precision level.

For smaller issuers (those with between 3,000 and 49,999 enrollees calculated statewide based on the benefit year being validated) with HCC failure rates above 1.644 standard deviations from the mean of any HCC failure rate group, and an assumed precision above the 10 percent target, we estimate approximate sample size ranges for issuer precision groups below:

- Issuers with 10 percent precision or lower.
- ++ 2019 approximate sample size: 200
- Issuers with precision between 10 percent and 20 percent.
- ++ 2019 approximate sample size range: 250 to 350
- Issuers with precision at 20 percent and above.
- ++ 2019 approximate sample size range: 400 to 500

For larger issuers (those with 50,000 or more enrollees calculated statewide based on the benefit year being validated) with HCC failure rates above 1.644 standard deviations of any mean HCC group failure rate, and an assumed precision above the 10 percent target, we estimate approximate sample size ranges for issuer precision groups below:

- Issuers with 10 percent precision or lower.
- ++ 2019 approximate sample size: 400
- Issuers with precision between 10 percent and 20 percent.
- ++ 2019 approximate sample size range: 450 to 650
- Issuers with precision at 20 percent and above.
- ++ 2019 approximate sample size range: 700 to 800

We estimate that approximately 70 of the 500 issuers expected to participate in risk adjustment data validation for the 2019 benefit year would be outside 1.644 standard deviations from the mean HCC failure rate. Of those issuers, we estimate that approximately 30 issuers would be smaller issuers, and approximately 40 issuers would have 50,000 or more enrollees calculated

statewide based on the benefit year being validated. Of the 30 smaller issuers, we estimate that approximately 50 percent, or 15 issuers, would have sample precision that meets or is better than the target precision of 10 percent, and therefore would not have their sample sizes increased above the current 200 enrollee sample size.

For our monetary and hourly burden estimates, we are incorporating labor and wage costs from the most recent premium stabilization programs PRA, “Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals” (CMS–1041/OMB control number 0938–1155). We are continuing to use the previously estimated annual hourly burden of approximately 740 hours and cost of \$45,430 for each issuer with a 200 enrollee sample. We estimate it will take 1 Medical Records and Health Information Technician (at an hourly rate of \$53.52) approximately 620 hours, 1 compliance officer (at an hourly rate of \$68.78) working 40 hours, and 2 operations managers working 40 hours each for a total of 80 hours (at an hourly rate of \$118.70), resulting in a combined total annual burden of 740 hours per issuer. We are using the same assumptions from the supporting statement to develop the below estimates, and are not changing burden estimates but are estimating the effect of changing sample sizes for affected issuers. Given that the total cost when the sample size is 200 enrollees is \$45,430 per issuer, we estimate that 150 additional enrollees per issuer over the 200 baseline number, or a sample size of 350 enrollees per issuer, would result in an annual increased burden of 555 hours, with an associated increase in cost of approximately \$34,072, and therefore, the estimated total annual burden per issuer with a sample of 350 enrollees would be 1,295 hours with an associated cost of approximately \$79,502 under this proposed approach.

We estimate that for the 15 smaller issuers with HCC failure rates above 1.644 standard deviations of any mean HCC group failure rate we believe will face a sample size increase as a result of poor precision, an average sample size of approximately 350 enrollees would result in an estimated overall annual burden increase of 8,325 hours, with an approximate increase in cost of \$511,083.

We are proposing to increase minimum sample sizes from 200 to 400 enrollees for all larger issuers (those with 50,000 or more enrollees calculated statewide based on the benefit year being validated) that are outside 1.644 standard deviations of the

mean HCC failure rate. As noted above, we estimate that approximately 40 larger issuers would have their sample sizes increased under this proposed approach. Of these 40 larger issuers, we estimate that approximately 35 would have good sample precision of 10 percent or lower and samples of 400 enrollees. Based on the assumptions above we estimate that a sample increase to 400 enrollees represents an annual increase of 740 hours and \$45,430 for each issuer, resulting in a total annual burden of 1,480 hours and associated cost of \$90,860 per issuer, and an aggregate burden increase of 25,900 hours and a cost of \$1,590,036 for those 35 issuers. We further estimate that 5 of the 40 larger issuers would have poor sample precision under this proposed approach, with at least one of those issuers having a precision above 20 percent, resulting in an average increased sample size for these issuers of approximately 500 enrollees. We estimate that the additional 300 enrollees (added to the current 200 enrollee sample size) would result in an additional annual burden of 1,110 hours and an associated cost of \$68,144 for each issuer. Therefore, for 5 issuers, we estimate an overall annual increase in burden of 5,550 hours with an associated cost of \$340,722. Therefore, for the approximately 55 issuers that would be impacted by the first proposed approach to modify the initial validation audit sample sizes, we estimate a total annual burden increase of approximately 39,775 hours, with an associated increase in cost of \$2,441,841 as a result of the proposed provision.

Alternatively, we are also considering an approach that would adjust an issuer’s sample size based on issuer size only. Therefore, we are also estimating the burden associated with developing the sample size based on issuer size only in the following groupings calculated based on the issuer’s total number of enrollees in all risk pools receiving risk adjustment transfers (calculated statewide based on the benefit year being validated). Below, we estimate hours and costs per issuer based on the labor and wage costs from the most recent premium stabilization programs’ PRA, which estimated hourly burden of approximately 740 hours and cost of \$45,430 per issuer with a 200 enrollee sample:

- Issuers with fewer than 51 enrollees (Note: These issuers would have no additional burden):
- ++ 2019 sample size for issuers with 50 enrollees or fewer: All enrollees (No more than 185 hours and \$11,357.50 per issuer)

- Issuers with 51–3,000 enrollees (Note: These issuers would have no additional burden):
- ++ 2019 approximate sample size for small issuers: 90 (333 hours and \$20,443.32 per issuer)
 - An estimated annual burden decrease per issuer of: 407 hours and \$24,986.28.
 - Issuers with 3,001–20,000 enrollees:
 - ++ 2019 approximate sample size for medium issuers: 250 (925 hours and \$56,787.00 per issuer)
 - An estimated annual burden increase per issuer of: 185 hours and \$11,357.40.
 - Issuers with 20,001–100,000 enrollees:
 - ++ 2019 approximate sample size for large issuers: 400 (1,480 hours and \$90,860.00 per issuer)
 - An estimated annual burden increase per issuer of 740 hours and \$45,430.
 - Issuers with 100,001 enrollees and above:
 - ++ 2019 approximate sample size for extra-large issuers: 500 (1,850 hours and \$113,575.00 per issuer)
 - An estimated annual burden increase per issuer of 1,110 hours and \$68,145.

If HHS were to finalize the proposal where any issuer can request larger sample sizes, the burden associated with that larger sample would align with the estimates set forth above, but would vary depending on the specific size that the issuer selects. For example, we estimate that a sample size of approximately 500 enrollees would require approximately 1,850 hours and cost approximately \$113,574.00, including an annual additional burden of 1,110 hours and an associated cost increase of \$68,144 per issuer. We assume that only larger issuers with more than 50,000 enrollees would choose to incur the additional burden required to elect to increase their sample size, and that 50 percent of the 40 larger issuers (20 issuers) that are outside 1.644 standard deviations would voluntarily choose to increase their sample size. As stated above, the burden associated with this option would vary depending on the specific size that the issuer selects. For example, we estimate that a sample size of 500 enrollees would require each issuer 1,850 hours with an associated cost of \$113,574, including an annual additional burden of 1,110 hours and associated cost increase of \$68,144 per issuer. If we assume 20 issuers would choose this proposed method, we estimate a total burden of 22,200 hours and an associated cost of \$1,362,888. We seek comment on this proposal and the estimated burdens discussed above.

If we finalize any of the proposed approaches to varying initial validation

audit sample sizes, we intend to amend the information collection currently approved under OMB control number 0938–1155 (CMS–10401—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment) to account for this additional burden.

D. ICRs Regarding Risk Adjustment Data Validation Exemptions (§ 153.630(g))

In proposed § 153.630(g)(3), we propose an exemption from risk adjustment data validation, beginning with the 2017 benefit year of risk adjustment data validation, if an issuer is in liquidation, or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited, provided that the issuer meets certain requirements. To qualify for this exemption, we propose that the issuer must provide to HHS, in a manner and timeframe to be specified by HHS, an attestation that the issuer will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited that is signed by an individual who can legally and financially bind the issuer. Beginning with the 2018 benefit year data validation, we propose that, to qualify for an exemption, an issuer also could not have been a positive error rate outlier in the prior benefit year's risk adjustment data validation. We anticipate that fewer than 10 issuers will submit this information to HHS annually. Under 5 CFR 1320.3(c)(4), this ICR would not be subject to the PRA, as it will affect fewer than 10 entities in a 12-month period.

We are also proposing to codify at § 153.630(g)(1) and (2) two exemptions for certain issuers from risk adjustment data validation that were finalized in the 2018 and 2019 Payment Notices. The reduction in burden for issuers who meet the criteria to be exempted under proposed § 153.630(g)(1) and (2) was estimated in those rules and have been incorporated into OMB Control Number 0938–1155 (CMS–10401—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment). Codifying these policies as part of HHS regulations as proposed in this rulemaking would not affect current burden estimates.

E. ICRs Regarding Upload of Risk Adjustment Data (§§ 153.610, 153.710)

We seek comment on extracting state and rating area data elements that issuers already submit to their EDGE servers beginning with the 2018 benefit year enrollee-level EDGE data. To extract these additional elements as part of the enrollee-level EDGE data, HHS would send a command to all issuers'

EDGE servers that issuers must execute. Because the additional data elements we solicit comment on extracting would not require issuers to collect or upload any additional data elements to their EDGE servers and would be added to the command execution for the enrollee-level EDGE data finalized in the 2018 Payment Notice, we do not believe it would impose any additional burden on issuers of risk adjustment covered plans described under the information collection currently approved under OMB Control Number 0938–1155 (CMS–10401—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment).

F. ICRs Regarding Agent or Broker Termination and Web Broker Data Collection (§ 155.220)

At § 155.220(c)(3)(i)(D)(1), we are proposing to require web-brokers that would like assisters to be permitted to use their respective websites to display all QHP data provided by the Exchange, consistent with the requirements of § 155.205(b)(1) and (c), including a standardized disclaimer provided by the Exchange if the web-broker website does not facilitate enrollment in all QHPs offered through the Exchange. The Exchange would provide the exact text for this disclaimer and the language would not need to be customized. The burden associated with this disclaimer is not subject to the Paperwork Reduction Act of 1995 in accordance with 5 CFR 1320.3(c)(2) because it does not contain a "collection of information" as defined in 44 U.S.C. 3502(3).

At § 155.220(c)(4)(i)(A), we propose to require web-brokers to provide HHS a list of agents or brokers that by contract or other arrangement use the web-broker's website to assist consumers with QHP selection or completion of the Exchange eligibility application, in a form and manner to be specified by HHS. Currently, § 155.220(c)(4)(i)(A) requires the provision of this information if requested by HHS. The burden on a web-broker to comply with this requirement is covered by the information collection currently approved under OMB control number 0938–1349 (CMS–10650—State Permissions for Enrollment in Qualified Health Plans in the Federally Facilitated Exchange & Non-Exchange Entities).

At § 155.220(g)(3)(ii), we are proposing to allow HHS to immediately terminate an agent's or broker's agreement(s) with the FFEs for cause with notice if an agent or broker fails to comply with the requirement to maintain the appropriate licensure in every state in which the agent or broker

actively assists consumers with enrolling in QHPs on the Exchange. An agent or broker whose agreement(s) with the FFEs are immediately terminated for cause under the new proposed paragraph (g)(3)(ii) would be able to request reconsideration under § 155.220(h). Although the process to request reconsideration imposes a small burden on agents or brokers subjected to terminations, we anticipate fewer than 10 terminations annually under this new authority. Under 5 CFR 1320.3(c)(4), this ICR would not be subject to the PRA as we anticipate it would affect fewer than 10 entities in a 12-month period.

At § 155.220(m)(3), we are proposing that the Exchange may collect from a web-broker during its registration with the Exchange under § 155.220(d)(1) or at another time on an annual basis, in a form and manner specified by HHS, information sufficient to identify the individuals who comprise the entity's corporate leadership or ownership, as well as any corporate or business relationships with other entities that may seek to register with the FFE as a web-broker. We believe the burden on a web-broker to comply with these requirements is covered by the information collection currently approved under OMB control number 0938-1349 (CMS-10650—State Permissions for Enrollment in Qualified Health Plans in the Federally Facilitated Exchange & Non-Exchange Entities). In the supporting statement for that information collection, we stated web-brokers will also be required to provide other documentation as requested in response to emerging compliance issues, for HHS to monitor compliance. The information we are proposing to collect based on proposed § 155.220(m)(3) is the type of information we anticipated when we referenced other documentation in response to emerging compliance issues.

G. ICRs Regarding Direct Enrollment Entity Standardized Disclaimer (§ 155.221)

At § 155.221(b)(2), we are proposing to require direct enrollment entities (both QHP issuers and web-brokers) to prominently display a standardized disclaimer, in the form and manner provided by HHS, to assist consumers in distinguishing between direct enrollment entity website pages that display QHPs and those that display non-QHPs during a single shopping experience. HHS would provide the exact text for this disclaimer and the language would not need to be customized. The burden associated with this disclaimer is not subject to the

Paperwork Reduction Act of 1995 in accordance with 5 CFR 1320.3(c)(2) because it does not contain a “collection of information” as defined in 44 U.S.C. 3502(3).

H. ICRs Regarding Special Enrollment Periods (§ 155.420)

The proposed special enrollment period at § 155.420(d)(6)(v) would be subject to pre-enrollment verification of eligibility for the FFEs. Where possible, the FFE makes every effort to verify an individual's eligibility for the applicable special enrollment period through automated electronic means instead of through an applicant's submission of documentation. Consistent with other special enrollment periods subject to pre-enrollment verification, individuals would be required to provide supporting documentation¹⁵³ within 30 days of plan selection.

We estimate an additional 4,700 consumers would submit documents annually to verify their eligibility to enroll through the proposed special enrollment period in the FFE, and that a consumer would, on average, spend approximately 1 hour gathering and submitting required documentation. Using the average hourly wage for all occupations (at an hourly rate of \$48.68), we estimate the opportunity cost to a consumer completing this task to be approximately \$48.68. We estimate the total annual burden on those consumers submitting documentation would be approximately 4,700 hours with an equivalent cost of approximately \$228,796.

We are revising the information collection currently approved under OMB control number 0938-1207 (CMS-10468—Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment) to account for this additional burden. SBEs that choose to operationalize the proposed special enrollment period are encouraged to follow the same approach for pre-enrollment verification of special enrollment period eligibility. We invite comments regarding the number of State Exchanges that anticipate adopting this approach.

¹⁵³ Consumer submitted documents currently accepted by the FFE for purposes of demonstrating prior coverage and verifying attested income are available at <https://www.healthcare.gov/help/prove-coverage-loss/> and <https://www.healthcare.gov/verify-information/documents-and-deadlines/>, respectively.

I. ICRs Regarding Eligibility Standards for Exemptions (§ 155.605)

We do not anticipate that the proposed amendment to § 155.605(e) would create additional costs on, or burdens to, the Exchanges. We anticipate it would decrease burden on those consumers who, when applying for a hardship exemption, choose to apply for the exemption through the IRS, saving them approximately 16 minutes since they would not be required to complete the exemption application or submit supporting documentation. HHS will continue to process exemptions under current regulations for all SBEs that elect this option, and anticipate a decrease in volume.

Based on historical data of the exemptions program and anticipating a decrease in individuals applying for exemptions as a result of the Tax Cuts and Jobs Act that reduced to \$0 the individual shared responsibility payment for months beginning after December 31, 2018, we estimate that approximately 50,000 individuals would apply for a hardship exemption annually through the FFE.¹⁵⁴ We expect 60 percent of those individuals would apply for a hardship exemption through IRS for 2018, totaling 30,000 requests.

We estimate that the annual reduction in burden for the expected 30,000 hardship exemptions through the IRS for 2018 would be approximately 8,100 hours. Using the average hourly wage for all occupations (at an hourly rate of \$48.68 per hour) we estimate that the annual reduction in cost for each consumer would be approximately \$13, and the annual cost reduction for all consumers applying for hardship exemptions through the IRS for 2018 would be approximately \$394,308.

We anticipate the burden would also be reduced for those consumers who currently apply through Connecticut.¹⁵⁵ Based on the population of Connecticut, we expect 330 consumers from that state will apply for a hardship exemption through the IRS for 2018, as opposed to through the state. We estimate that the annual reduction in burden for the 330 hardship exemptions through the IRS would be approximately 89 hours. Using the average hourly wage for all occupations (at an hourly rate of \$48.68 per hour) we estimate the annual reduction in cost for each consumer

¹⁵⁴ Although the Tax Cuts and Jobs Act reduces to \$0 the individual shared responsibility payment for months beginning after December 31, 2018, individuals may still have a need to seek a hardship exemption for 2019 and future years due to a lack of affordable coverage based on projected income.

¹⁵⁵ HHS processes exemptions for all SBEs except Connecticut.

would be approximately \$13, and the annual cost reduction for all consumers in Connecticut applying for a hardship

exemption through IRS for 2018 would be approximately \$4,337.

J. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 13—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control number	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total cost (\$)
147.106(e)(5)(i)(A)	0938-NEW	* 520	22,700,000	22	11,444	\$66.83	\$8,505,204
147.106(e)(5)(i)(B)	0938-NEW	* 520	22,700,000	18	9,360	72.98	8,423,834
156.122(d)(3)	0938-NEW	66	66	42	2,772	50.49	139,954
153.630(b)	0938-1155	55	55	723	39,775	68.78	2,441,841
155.420	0938-1207	4,700	4,700	1	4,700	48.68	228,796
Total	5,341	45,404,821	68,051	19,739,629

* Denotes the same entities. For purposes of calculating the total, this value is used only once.

** There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 13.

K. Submission of PRA-Related Comments

We have submitted a copy of this proposed 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 the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit CMS’s website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS-9926-P), the ICR’s CFR citation, CMS ID number, and OMB control number.

ICR-related comments are due March 25, 2019.

V. 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 proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This rule proposes standards related to the risk adjustment program for the 2020 benefit year, clarifications and improvements to the risk adjustment

data validation program, as well as certain modifications that will promote transparency, innovation in the private sector, reduce burden on stakeholders, and improve program integrity. The Premium Stabilization Rule, previous Payment Notices, and recently released final¹⁵⁶ rules provided details on the implementation of the risk adjustment program, including the specific parameters applicable for the 2014, 2015, 2016, 2017, 2018, and 2019 benefit years. This rule proposes additional standards related to mid-year formulary changes, essential health benefits; cost-sharing parameters; the Exchanges, including exemptions, eligibility and enrollment; calculation of the premium adjustment percentage; and FFE and SBE-FP user fees. The rule also proposes that QHP issuers that elect to offer coverage for non-Hyde abortion services in QHPs offered on the Exchanges must also offer at least one otherwise identical QHP that does not offer non-Hyde abortion coverage throughout each service area that the QHP issuer offers plans covering non-Hyde abortion services, to the extent permissible under state law.

B. Overall Impact

We have examined the impacts of this 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 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year).

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)

¹⁵⁶ Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and Patient Protection and Affordable Care Act; Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year, Final Rule, 83 FR 63419 (Dec. 10, 2018).

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 RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a "significant" regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of \$100 million or more in at least 1 year, and therefore, meets the definition of "significant rule" under Executive Order 12866. Therefore, HHS has provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The provisions in this proposed rule aim to ensure taxpayer money is more appropriately spent and that states have additional flexibility and control over their insurance markets. They would reduce regulatory burden, reduce administrative costs for issuers and states, and would lower net premiums for consumers. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage. Although there is some uncertainty regarding the net effect on enrollment and premiums, we anticipate that the provisions of this proposed rule would help further HHS's goal of ensuring that all consumers have access to quality, affordable health care; that markets are stable; and that Exchanges operate smoothly.

We believe the proposal at § 156.280(c)(3) requiring issuers of QHPs that provide coverage of certain abortions to provide at least one otherwise identical QHP that omits coverage of such abortion services in a separate QHP throughout each service area in the Exchange in which the QHP issuer offers plans covering non-Hyde abortion services, to the extent permissible under state law, would increase consumer choice by requiring certain QHP issuers to offer additional QHPs. This proposal would especially benefit those consumers who have religious or conscience objections to

abortion by providing them the option to choose a compatible plan without non-Hyde abortion coverage. However, we understand that this proposal may also potentially reduce the availability of non-Hyde abortion coverage in insurance, thereby increasing out-of-pocket costs for some women seeking those services. The proposal may also increase costs and regulatory and administrative burdens for certain QHP issuers and states, and could result in increased costs for some consumers. However, we believe that the need to promote consumer choice and enrollment offsets such burdens.

HHS anticipates that the provisions of this proposed rule will help further the HHS's goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices, that the insurance market offers choices, and that states have more control and flexibility over the operation and establishment of Exchanges. Affected entities such as direct enrollment entities, and QHP issuers would incur costs to comply with the proposed new provisions, for example, those related to direct enrollment; and states would incur costs if they choose to implement the proposed special enrollment period. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular A-4, Table 14 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This proposed rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this proposed rule. The effects in Table 14 reflect qualitative impacts and estimated direct monetary costs and

transfers resulting from the provisions of this proposed rule for health insurance issuers and consumers. The annualized monetized costs described in Table 14 reflect direct administrative costs and savings to health insurance issuers and consumers as a result of the proposed provisions regarding special enrollment periods, use of direct enrollment entity application assisters to carry out responsibilities currently performed by agents or brokers, and applying for hardships exemptions. The annual monetized transfers described in Table 14 include changes to costs associated with the risk adjustment user fee paid to HHS by issuers and the potential increase in PTC for those qualifying individuals that use the new SEP. We are proposing the risk adjustment user fee of \$2.16 per billable member per year for the 2020 benefit year to operate the risk adjustment program on behalf of states,¹⁵⁷ which we estimate to cost approximately \$50 million in benefit year 2020. We expect risk adjustment user fee transfers from issuers to the federal government to increase by \$10 million, compared to the \$40 million estimated for the 2019 benefit year; this increase is included in Table 14. Additionally, we are proposing a lower FFE user fee rate of 3.0 percent for the 2020 benefit year, which is lower than the 3.5 percent FFE user fee rate finalized for 2014 to 2019 benefit years. We also propose to lower SBE-FP user fee rate to 2.5 percent for the 2020 benefit year from the 3.0 percent SBE-FP user fee rate we finalized for the 2019 benefit year. We do not expect this change in the SBE-FP user fee rate to alter transfers previously estimated from the FFE and SBE-FP issuers. We are estimating FFE and SBE-FP user fee transfers similar to those estimated for prior benefit years, and therefore, there would be no changes to transfers from issuers to the federal government due to the proposed lower FFE and SBE-FP user fee rates. Also, we propose a change to the premium measure we use to calculate the premium adjustment percentage, which would result in a proposed premium adjustment percentage of 1.2969721275 percent for the 2020 benefit year.

TABLE 14—ACCOUNTING TABLE

Benefits

Qualitative:

- Greater market stability resulting from updates to the risk adjustment methodology.

¹⁵⁷ As noted earlier in this proposed rule, no state has elected to operate the risk adjustment program

for the 2020 benefit year; therefore, HHS will

operate the program for all 50 states and the District of Columbia.

TABLE 14—ACCOUNTING TABLE—Continued

- Potential increased enrollment in the individual market stemming from lower premiums due to proposed expansion of direct enrollment opportunities, leading to improved access to health care for the previously uninsured, especially individuals with medical conditions, which will result in improved health and protection from the risk of catastrophic medical expenditures.
- Greater continuity of coverage for consumers related to the proposed special enrollment period.
- Reduced Navigator training compliance burden and increased flexibility in training design for Exchanges by streamlining the existing training topics into four broad categories.
- Reduced burden to FFE Navigators by making the duties listed at § 155.210(e)(9) permissible for FFE Navigators, not required.
- Strengthened program integrity related to the proposals regarding agents and brokers and direct enrollment entities, as well as from the proposed sampling changes for the risk adjustment data validation program.
- Reduction in burden associated with risk adjustment data validation for issuers eligible for the proposed liquidation exemption.
- Potential reduction in economic distortions, and improvement in economic efficiency as a result of the reduction in Exchange enrollment due to the change in the method of calculating the premium adjustment percentage.

Costs	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized (\$/year)	\$1.57	2018	7	2019–2023
	1.84	2018	3	2019–2023

Quantitative:

- Costs incurred by issuers and consumers to comply with provisions in the proposed rule related to mid-year formulary changes, varying the risk adjustment initial validation audit sample size, and special enrollment periods.
- Reduction in burden and costs for consumers applying for hardship exemptions through IRS.
- Reduction in burden and cost for direct enrollment entities that choose to use direct enrollment entity application assisters to carry out responsibilities currently performed by agents or brokers.
- Regulatory familiarization costs.

Qualitative:

- Costs to issuers due to increases in providing medical services if health insurance enrollment increases.
- Potential costs to Exchanges that opt to implement special enrollment period for qualified individuals who experience a decrease in household income and are newly determined eligible for APTC, and to issuers for processing related enrollments and terminations.
- Costs to health insurance issuers for implementing risk adjustment data validation to ensure the integrity of the risk adjustment transfers.

Transfers	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Federal Annualized Monetized (\$/year)	\$828.3	2018	7	2019–2023
	848.4	2018	3	2019–2023

Quantitative:

- Transfer from health insurance issuers to the federal government of \$50 million as risk adjustment user fees for 2023 (the amount will increase by \$10 million from that previously estimated for 2020–2022).
- Transfer from federal government of \$15.3 million in premium tax credits to consumers enrolling through proposed special enrollment period.
- Health Insurance Providers Fees of approximately \$100 million in 2023, which is a transfer from issuers to the federal government, and Employer Shared Responsibility Payments of \$100 million per year between 2020 and 2023, which is a transfer from employers to the federal government.
- Reductions in federal premium tax credit spending of approximately \$900 million in 2020 and 2021, and \$1 billion in 2022 and 2023, which is a transfer from consumers to the federal government.
- Between 2020 and 2023, net premium increases of approximately 1 percent or \$181 million in additional net premiums per year, which is a transfer from consumers and the federal government to issuers.

Qualitative:

- The net effects on premiums based on proposed changes at § 156.130(h) is uncertain.
- Potential increase in federal and state uncompensated care costs as a result of lower Exchange enrollment due to the change in the method of calculating the premium adjustment percentage.

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office’s (CBO) analysis of the PPACA’s impact on federal spending, revenue collection, and insurance enrollment. The PPACA transitional reinsurance and temporary risk corridors programs ended after the 2016 benefit year. Therefore, the costs associated with those programs are not included in Tables 14 or 15 for fiscal years 2020–2023. Table 15 summarizes the effects of the risk adjustment program on the federal budget from

fiscal years 2019 through 2023, with the additional, societal effects of this proposed rule discussed in this RIA. We do not expect the provisions of this proposed rule to significantly alter CBO’s estimates of the budget impact of the risk adjustment program that is described in Table 15. We note that transfers associated with the risk adjustment program were previously estimated in the Premium Stabilization Rule; therefore, to avoid double-counting, we do not include them in the

accounting statement for this proposed rule (Table 14).

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on this internal analysis, we anticipate that the quantitative effects of the provisions proposed in this rule are consistent with our previous estimates in the 2019 Payment Notice for the impacts associated with the APTC, the premium stabilization programs, and FFE user fee requirements.

TABLE 15—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT PROGRAMS FROM FISCAL YEAR 2019–2023, IN BILLIONS OF DOLLARS

Year	2019	2020	2021	2022	2023	2019–2023
Risk Adjustment Program Payments	5	6	6	6	7	30
Risk Adjustment Program Collections *	5	6	6	7	7	31

Note 1: Risk adjustment program payments and receipts lag by one quarter. Receipts will fully offset payments over time.

Note 2: The CBO score reflects an additional \$1 million in payments in FY 2018 that are collected in prior fiscal years. CBO does not expect a shortfall in these programs.

Source: Congressional Budget Office. *Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2018 to 2028* Table 2. May 2018. Available at <https://www.cbo.gov/system/files?file=2018-06/51298-2018-05-healthinsurance.pdf>.

1. Guaranteed Renewability of Coverage (Parts 146, 147, and 148)

In §§ 146.152, 147.106, and 148.122, we propose to allow issuers to make certain mid-year formulary changes in an effort to optimize the use of new generic drugs as they become available. At §§ 146.152(f)(5), 147.106(e)(5), and 148.122(g)(5), we propose to allow issuers, subject to applicable state law, to remove the brand name drug from the formulary or move it to a higher cost-sharing tier when a generic equivalent becomes available and is added to the formulary. In the Collection of Information section of this proposed rule, we estimate the cost to issuers to provide the related notices. We believe that allowing issuers to make mid-year formulary changes will result in curbing the cost of prescription drug coverage.

2. Risk Adjustment

The risk adjustment program is a permanent program created by section 1343 of the PPACA that transfers funds from issuers with lower-than-average risk populations to issuers with higher-than-average risk populations in the individual, small group and merged markets, (as applicable) inside and outside the Exchanges. We established standards for the administration of the risk adjustment program in subparts A, B, D, G, and H of 45 CFR part 153.

A state approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. Consistent with 45 CFR 153.610(f), if HHS operates risk adjustment on behalf of a state, it will fund its risk adjustment program operations by assessing a risk adjustment user fee on issuers of risk adjustment covered plans. For the 2020 benefit year, we estimate that the total cost for HHS to operate the risk adjustment program on behalf of all states would be approximately \$50 million, and that the risk adjustment user fee would be approximately \$2.16 per billable member per year. The updated cost estimates attribute all costs related to the EDGE server data

collection and data evaluation (quantity and quality evaluations) activities to risk adjustment alone rather than sharing them with the reinsurance program, which is no longer operational. Previously, we had collected amounts for reinsurance administrative expenses which would partially fund contracts that were used for both the risk adjustment and reinsurance programs. Now, those costs are borne by the risk adjustment program alone. Additionally, based on experience with the risk adjustment data validation program development and execution, including development of the new risk adjustment data validation audit tool and additional contractor support for processing risk adjustment data validation discrepancies and appeals, we estimate higher costs associated with the risk adjustment data validation program. Finally, we are incorporating the full amount of eligible personnel and administrative costs associated with risk adjustment program development and operations, including indirect costs, in the risk adjustment user fee for the 2020 benefit year. The personnel and administrative costs included in the calculation of the 2019 benefit year risk adjustment user fees in the 2019 Payment Notice final rule incorporated only a portion of the eligible personnel costs, and excluded indirect costs. Finally, we estimated similar billable member month enrollment for the 2020 benefit year as the most recent 2017 benefit year individual and small group market enrollment.

We believe that the proposed approach of blending the coefficients calculated from the 2016 and 2017 benefit year enrollee-level EDGE data with the 2017 MarketScan® data would provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2019 benefit year to the 2020 benefit year due to differences in the datasets' underlying populations. We solicit comment on extracting state and rating area information that issuers already collect and upload to the EDGE servers.

We believe these geographic data elements could better inform recalibration of the HHS-operated risk adjustment program, the AV Calculator and methodology, and other HHS programs for the individual and small group markets, as well as provide more useful information to researchers or other qualified requestors as to the state of the individual, small group and merged markets if included as part of the proposed EDGE enrollee-level limited data set. Furthermore, we propose to use the enrollee-level EDGE dataset and reports extracted from issuer EDGE servers to calibrate and operationalize HHS programs for the individual and small group (including merged) market programs, as well as to more broadly conduct policy analysis for the individual and small group (including merged) markets.

3. Risk Adjustment Data Validation (§ 153.630)

Under § 153.630, we are proposing several changes to the requirements for risk adjustment data validation. Beginning with the 2019 benefit year of risk adjustment data validation,¹⁵⁸ we propose to vary the initial validation audit sample size based on HCC failure rates, sampled precision, and issuer size. We also outline an alternative proposal that would vary sample size by issuer size only, and we are considering permitting issuers of any size and with any HCC failure rate to request a larger sample size.

In the Collection of Information section of this proposed rule, we estimate the increase in administrative burden that could result from all of the approaches under consideration to vary the initial validation audit sample size. We note that, in certain cases, while the administrative burden would increase as an issuer's sample size increases, we believe that any increase in sample sizes would produce more precise risk adjustment data validation results which are used to adjust risk scores and

¹⁵⁸ Activities related to the 2019 benefit year risk adjustment data validation will generally begin in the second quarter of the 2020 calendar year.

associated risk adjustment transfers. While this could affect the data validation adjustments to risk adjustment transfers for an individual issuer, we do not expect an impact on aggregate risk adjustment transfer adjustments based on HCC failure rates as a result of the proposed modifications to the initial validation audit sample size methodology.

Because issuers are already required to provide the initial and second validation audit entities with all documentation necessary to complete the audits, the proposed changes to the pairwise means test that would increase the second validation audit sample to the full 200 enrollee sample size in certain cases would not increase burden on issuers, as the second validation audit is conducted by HHS, not issuers. Instead, we believe that increasing the second validation audit sample size to the full initial validation sample of 200 enrollees, in certain cases, may increase the costs to the federal government of conducting the second validation audit, but we also believe that the benefits from improving the process for validating the second validation audit results and the accompanying precision it would bring to risk score error rate adjustments would outweigh the increased costs to the federal government and better ensure the integrity of the risk adjustment program.

We believe that incorporating prescription drug categories in the error estimation methodology for risk adjustment data validation would add complexity, but revising this calculation would align risk adjustment data validation with the accompanying risk adjustment program requirements, as the HHS-operated risk adjustment methodology started incorporating prescription drug factors beginning with the 2018 benefit year. The purpose of this proposed alignment would be to ensure that prescription drugs are being validated as part of risk adjustment data validation process. Because HHS calculates issuers' error rates, issuers will not incur additional expenses as a result of revisions to the error estimation calculation,¹⁵⁹ but HHS and its second validation auditor will incur expenses to update its methodology and its calculation and make the necessary adjustments to systems to modify the

procedures for calculating the error estimation.

The exemptions in this proposed rule for risk adjustment data validation codify two policies finalized in the 2018 and 2019 Payment Notices and also include one new proposed exemption policy for issuers in or entering liquidation. The impact of the previously finalized exemptions was addressed in the 2018 and 2019 Payment Notices. We believe that the number of issuers that will qualify for the proposed exemption for issuers in liquidation will be very small each year, and therefore, we believe that the overall reduction in burden will be limited. However, those issuers that are exempted from risk adjustment data validation would have less burden and administrative costs than an issuer that is not exempt from these requirements.

4. Ability of States To Permit Agents and Brokers To Assist Qualified Individuals, Qualified Employers, or Qualified Employees Enrolling in QHPs (§ 155.220)

In § 155.220(c)(3)(i)(D)(1), we are proposing to require web-brokers that would like assisters to be permitted to use their non-Exchange websites when assisting with Exchange applications or QHP enrollments to display all QHP data provided by the Exchange consistent with the requirements of § 155.205(b)(1) and (c). We are not proposing to require web-broker websites that assisters would be permitted to use to facilitate enrollment in all QHPs offered through the Exchange. However, web-broker websites that do not facilitate enrollment in all QHPs would be required to identify to consumers the QHPs, if any, for which the web-broker website does not facilitate enrollment by prominently displaying a standardized disclaimer, in the form and manner provided by the Exchange, stating that enrollment in such QHPs can be completed through the Exchange and providing a link to the Exchange. Consistent with the existing requirement at § 155.220(c)(i)(F), all web-brokers, including those that would like assisters to be permitted to use their non-Exchange websites, must provide consumers with the ability to withdraw from the entity's non-Exchange website and use the Exchange at any time. We note that web-brokers may obtain all QHP information they would be required to display for assisters to be permitted to use their non-Exchange websites in FFEs and SBE-FPs by integrating with the FFEs' Marketplace application programming interface (API). In combination with this

proposal, we have proposed to reverse our prior policy prohibiting assisters from using web-broker websites to assist consumers in most circumstances. It is difficult to quantify the number of web-brokers that would modify their websites to permit assisters to use them or the number of assisters that would use web-broker websites. However, since both avenues are optional, we do not anticipate any negative impact on either community. Instead, we see this as increasing flexibility for both web-brokers and assisters, as well as creating the potential for new mechanisms for consumers to receive assistance with Exchange eligibility applications and QHP enrollments.

In § 155.220(c)(3)(i), we propose a new paragraph (c)(3)(i)(L) to prohibit web-brokers from displaying QHP recommendations on their websites based on compensation received from QHP issuers. Web-brokers often collect certain information from consumers and on the basis of that information display or sort QHPs, or apply a score to all available QHPs, indicating which QHP they believe is the best option for those consumers. We support the development and use of innovative consumer-assistance tools that may help consumers select QHPs that best fit their needs. However, we believe such recommendations should be based on information consumers have provided to web-brokers and not based on compensation received from QHP issuers when consumers enroll in their plans. We are not aware of any web-brokers currently recommending QHPs based on compensation received from QHP issuers, so we expect the impact of this proposal to be very limited. This proposal also helps support the use of web-broker websites by FFE and SBE-FP assisters to ensure assisters can continue to meet their statutory and regulatory obligations.

In § 155.220(c)(4)(i)(A), we propose to require web-brokers to provide HHS with a list of agents or brokers who, through a contract or other arrangement, use the web-brokers' websites to assist consumers with QHP selection or completion of the Exchange eligibility application, in a form or manner to be specified by HHS. The authority currently exists for HHS to obtain this information by request. However, due to the trend of increased use and expansion of direct enrollment pathways, we believe it is appropriate to collect this information proactively, so that we may respond more efficiently and effectively to any potential instances of noncompliance that may involve agents or brokers using a web-broker's direct enrollment pathway.

¹⁵⁹ 45 CFR 153.630(b)(7)(iii) states that the risk score of each enrollee in the sample must be validated by, beginning with the 2018 benefit year, validating enrollee health status through review of all relevant paid pharmacy claims. Under the 2018 Payment Notice (81 FR 94058 to 94105), we previously revised the estimated burden for reviewing and validating pharmacy claims for risk adjustment data validation.

Having this information will, for example, enable us to identify more quickly whether noncompliance is attributable to a specific individual or individuals, instead of the web-broker entity. We anticipate releasing guidance that would require the list to include, at minimum, each agent's or broker's name, state(s) of licensure, and National Producer Number. We believe the burden associated with this data collection will be relatively limited, as we understand that web-brokers collect and store this information as part of their normal business operations to identify individual agents or brokers utilizing their systems. The burden related to this provision is discussed previously in the Collection of Information Requirements section.

In § 155.220(g)(3)(ii), we propose to allow HHS to immediately terminate an agent's or broker's agreement if the agent or broker fails to maintain applicable state licensure as an agent, broker, or insurance producer in every state in which the agent or broker actively assists consumers with applying for APTC or CSRs or with enrolling in QHPs through the FFEs or SBE-FPs. State licensure for agents and brokers in every state in which they are assisting consumers is a fundamental consumer protection and critical for program integrity. It has been a requirement in the FFE agreements with agents and brokers since the inception of the FFEs, and is adhered to by the overwhelming majority of agents and brokers. Therefore, we believe the impact of this provision on agents and brokers would be minimal, but the proposal would benefit consumers who might otherwise interact with unlicensed individuals and would improve Exchange program integrity.

In § 155.220(k), we are proposing to add a new paragraph (k)(3) that would allow HHS to immediately suspend an agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction. This proposed language is identical to an existing provision intended to apply to web-brokers at § 155.220(c)(3)(i)(L) and a similar provision applicable to QHP issuers participating in direct enrollment at § 156.1230(b)(1). Those provisions are proposed to be replaced with a very similar new requirement that would apply to both types of direct enrollment entities in proposed § 155.221(d). Because the potential risks posed by agents and brokers with access

to FFE systems are similar to those posed by web-brokers and QHP issuers participating in direct enrollment, we believe this change is necessary to provide a uniform process and ability to protect Exchange systems and operations from unacceptable risks, as well as to protect sensitive consumer data. We note that agents and brokers whose ability to transact information with the Exchange is suspended under this proposed authority would remain registered and authorized to assist consumers using the Marketplace (or side-by-side) pathway, unless and until their agreements were suspended or terminated under § 155.220(f) or (g). We believe this proposed authority would be used infrequently and only in cases where there would likely be the reasonable basis to suspend their agreements under § 155.220(g)(5)(i) but there is a need to take immediate action to protect sensitive consumer data or Exchange systems and operations. Therefore its effect on agents and brokers is expected to be relatively limited.

In § 155.220(m)(1), we propose to allow a web-broker's agreement to be suspended or terminated for cause under § 155.220(g), and a web-broker to be denied the right to enter into agreements with the FFEs under paragraph (k)(1)(i) of this section based on the actions of its officers, employees, contractors, or agents, even if those persons are not agents or brokers registered with the FFE. In § 155.220(m)(2), we propose to allow a web-broker's agreement to be suspended or terminated under § 155.220(g), and for the entity to be denied the right to enter into agreements with the FFEs under § 155.220(k)(1)(i), if it is under the common ownership or control, or is an affiliated business, of another web-broker that has had its agreement suspended or terminated for cause. We expect these provisions to have limited impact, as they are designed to protect program integrity and will only be utilized in limited cases when there is evidence of significant misconduct or non-compliance. In those cases, we anticipate benefits to consumers stemming from our enhanced ability to address program integrity concerns and non-compliance issues. In § 155.220(m)(3), we propose to require the Exchange to collect information from a web-broker sufficient to establish the identities of individuals who comprise its corporate leadership and to determine any business relationships with other entities that may seek to register with the Exchange as web-brokers. These provisions are also

intended to protect program integrity by enabling the Exchange to have information necessary to determine if any individuals seeking to be web-brokers are attempting to circumvent a previous termination or suspension for cause of an FFE agreement(s). The burden related to this provision is discussed previously in the Collection of Information Requirements section.

5. Direct Enrollment (§§ 155.20, 155.220, 155.221, 155.415, 156.1230)

The proposed changes to § 155.220 are discussed above. In § 155.221, we propose to amend and redesignate the existing paragraphs (a), (b) and (c) to new proposed paragraphs (e), (f), and (g). In proposed new § 155.220(e), we propose to add language to require that the third-party entities that conduct annual reviews of direct enrollment entities to demonstrate operational readiness consistent with newly proposed § 155.221(b)(4)¹⁶⁰ be independent of the entities they are auditing. We are proposing this change because we believe an independent audit is less likely to be influenced by a direct enrollment entity's business considerations and therefore is more reliable. We expect no impact from this provision as it was included as a requirement in the agreements we executed with direct enrollment entities subject to these audits for plan year 2019. We also propose to clarify in proposed § 155.221(e) that an initial audit is required, in addition to subsequent annual audits. This clarification does not represent a change from the current approach, as direct enrollment entities are currently required to demonstrate operational readiness before their websites may be used to complete QHP selections.¹⁶¹ Therefore we anticipate no impact of this proposed change. In proposed § 155.221(f), we propose to require that a written agreement must be executed between a direct enrollment entity and its auditor stating that the auditor will comply with the requirements of paragraph (f). We are proposing this new requirement because we believe the most effective way to ensure a direct enrollment entity has the necessary control and oversight over its auditor to ensure compliance with the applicable standards in § 155.221 is for those standards to be memorialized in a written agreement. We expect most, if

¹⁶⁰ Direct enrollment operational readiness review requirements are currently captured at 45 CFR 155.220(c)(3)(i)(K) for web-brokers and 156.1230(b)(2) for QHP issuers.

¹⁶¹ See 45 CFR 156.1230(b)(2) for issuers participating in direct enrollment and 45 CFR 155.220(c)(3)(i)(K) for web-brokers.

not all, direct enrollment entities already execute written agreements with their contractors that would incorporate any regulatory requirements that fall within the scope of the work the contractor is performing for the entity, so we expect little to no impact from this proposed change.

In the new § 155.221(a), we propose to codify in regulation the types of entities the FFEs will permit to offer non-Exchange websites to facilitate direct enrollment in coverage offered through the Exchange in a manner that is considered to be through the Exchange. There are two types of entities that are authorized by the FFEs to offer direct enrollment pathways: QHP issuers and web-brokers. We expect this provision to have little or no impact as QHP issuers and web-brokers are already authorized by the FFEs to participate in direct enrollment.

In the new § 155.221(b), we propose to establish and consolidate certain requirements that apply to all direct enrollment entities. Specifically, we propose to add in § 155.221(b)(1) that QHPs and non-QHPs must be displayed and marketed on separate website pages on the direct enrollment entity's non-Exchange website. We consider this a clarification of existing standards that would have minimal impact on direct enrollment entities, and would minimize the chance that consumers are confused by the display or marketing of QHPs and non-QHPs on a single website page. In the new § 155.221(b)(2) we propose to require the prominent display of a standardized disclaimer in a form and manner provided by HHS. Similar uniform disclaimer requirements already exist for all direct enrollment entities. As a result, and because we will provide the disclaimer text, we expect the overall impact of this provision to be minimal. In the new § 155.221(b)(3), we propose to limit the marketing of non-QHPs during the Exchange eligibility application and QHP selection process on direct enrollment entities' websites in a manner that minimizes the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not. This will also assist consumers in understanding the applicability of APTC and CSRs that they may be eligible for. Most direct enrollment entities have refrained from marketing non-QHPs in conjunction with QHPs citing a lack of clear guidance. Therefore we expect the impact of this provision to be minimal, and to be perceived as allowing increased flexibility. In the new § 155.221(b)(4), we propose to consolidate a provision requiring direct

enrollment entities demonstrate operational readiness and compliance with applicable requirements prior to the entities' websites being used to complete an Exchange eligibility application or a QHP selection. Because this is an existing requirement, we expect no impact.

In the new § 155.221(c), we propose that the authority to use application assisters and the corresponding requirements when doing so apply for all issuers and direct enrollment entities and not solely QHP issuers. We have proposed a new definition of "direct enrollment entity application assister" in § 155.20 that mirrors the existing definition of "issuer application assister", as well as amendments to § 155.415 to capture the requirements for entities using application assisters that align with the existing requirements currently in § 156.1230(a)(2) for QHP issuer application assisters. We do propose one significant deviation from the existing requirements for application assisters. Currently, § 156.1230(a)(2)(i) requires all application assisters to receive training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations. Licensed agents and brokers currently assisting consumers with QHP enrollment through the FFEs or SBE-FPs must have credentials to access FFE systems to offer that assistance. Those credentials are obtained during the FFE registration and training processes for agents and brokers. For application assisters to have similar access to FFE systems, so that they are also able to assist consumers as described here and in the preamble above, they would need credentials similar to those obtained by agents and brokers during FFE registration and training. Therefore, we propose to require that application assisters providing assistance in the FFEs and SBE-FPs comply with this training requirement by completing a similar registration and training process, in a form and manner to be specified by HHS, so that they would have the necessary credentials to provide consumer assistance. This proposed new training and registration requirement for application assisters is captured in the new proposed § 155.415(b)(1). The burden placed on application assisters to complete the FFE training may exceed what may have otherwise existed if direct enrollment entities were developing and managing their own training programs. However, by requiring the FFE training to be completed by application assisters assisting consumers in the FFEs and

SBE-FPs, it would relieve direct enrollment entities from the burdens associated with having to develop and manage their own training programs. Importantly, FFE systems would require this approach to comply with system security requirements and to enable application assisters to meaningfully be able to assist consumers in the FFEs and SBE-FPs. Therefore, taken together, we believe the net burden associated with this proposal would be minimal and would be acceptable to participating direct enrollment entities that elect to use application assisters, when permitted under state law. The reason we believe the net burden would be minimal is because the bulk of time associated with application assisters completing the training requirement would likely be comparable whether the training is developed and administered by direct enrollment entities or by HHS. However, there would likely be a small increase in the amount of time application assisters would have to devote to the registration process apart from training, specifically to creating an FFE account and completing identity proofing. In contrast, there would likely be a substantial reduction in burden on direct enrollment entities, because they would not have to develop and manage their own training programs. Instead they would be able to simply confirm their application assisters have completed the FFE registration and training process.

We estimate allowing QHP issuers to use application assisters in the FFEs and SBE-FPs, and expanding that option to other issuers and web-brokers will provide cost savings to these entities. It is difficult to precisely estimate the number of applications for which a direct enrollment entity application assister provided help may be submitted. However, based on available data, we estimate that approximately 980,000 agent or broker-assisted direct enrollment applications will be submitted in plan year 2019. We estimate that it would take an insurance sales agent¹⁶² (at an hourly rate of \$64.42) one hour to complete an application. We do not have information related to the number of states that would allow for unlicensed application assisters, as well as how many direct enrollment entities would hire application assisters or train existing staff as application assisters. Therefore, we estimate that half of assisted direct enrollment applications would be completed with the assistance of an

¹⁶² Bureau of Labor Statistics mean hourly wage for an Insurance Sales Agent (Occupational Code 41-3021) at \$32.21 an hour, plus 100 percent fringe.

application assister instead of an agent or broker. Based on these assumptions, we estimate that it would take an insurance claims and policy processing clerk¹⁶³ (at an hourly rate of \$39.52) one hour to complete each application. Thus, we estimate that the applications for 490,000 applicants would result in an estimated total burden of approximately 490,000 hours with an associated cost of approximately \$19,364,800. If the applications are completed by an agent or broker instead, the total cost would be approximately \$31,565,800. Based on these assumptions, we estimate an overall annual savings of approximately \$12.2 million for direct enrollment entities using application assisters instead of only agents or brokers. In addition, we expect that the time that agents or brokers may otherwise have spent assisting consumers with their eligibility applications would often instead be devoted to assisting more consumers with plan selection and finalizing their enrollments. As a result, we expect this policy may also result in an overall increase in enrollment through the FFEs and SBE-FPs. Lastly, these proposals provide increased flexibility and a level playing field to all direct enrollment entities and issuers.

In the new § 155.221(d), we propose to consolidate existing authority to immediately suspend a direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the Exchange's ability to make accurate eligibility determinations, or Exchange operations or systems until such circumstances are remedied or sufficiently mitigated to HHS's satisfaction. We expect little or no impact from this proposal, since this is largely based on an existing authority.

We also propose to codify new definitions for the following terms in § 155.20: Direct enrollment entity, direct enrollment technology provider, and web-broker. We propose to define "direct enrollment entity" as an entity that an Exchange permits to assist consumers with direct enrollment in QHPs offered through an Exchange in a manner considered to be through the Exchange as authorized by §§ 155.220(c)(3), 155.221, or 156.1230. We expect no impact from this proposal as it merely codifies a definition for the term in such a way that the entities that are currently authorized by the FFE to host a direct enrollment pathway are

direct enrollment entities. We also propose to amend § 155.20 to define "direct enrollment technology provider" as a type of web-broker business entity that is not a licensed agent, broker, or producer under state law and has been engaged or created by, or is owned by, an agent or broker, to provide technology services to facilitate participation in direct enrollment as a web-broker in accordance with §§ 155.220(c)(3) and 155.221. There may be instances when an individual agent or broker, a group of agents or brokers, or an agent or broker business entity engages the services of or creates a technology company that is not licensed as an agent or broker to assist with the development and maintenance of a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. In such cases, when the technology company is not itself licensed as an insurance agency or brokerage, we propose that these technology companies will be considered a type of web-broker that must comply with applicable web-broker requirements under §§ 155.220 and 155.221, unless noted otherwise. We expect no new burden associated with this requirement as it merely allows some flexibility in terms of how licensed agents or brokers may organize their businesses or pursue business relationships when seeking to become web-brokers. We also propose to codify a definition of "web-broker" as an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchanges as described in §§ 155.220(c)(3) and 155.221. As explained in the preamble, we also propose to define the term "web-broker" to generally include direct enrollment technology providers. Importantly, if this definition is finalized as proposed it would replace HHS's current web-broker definition, which is slightly different. However, we expect no impact, because all existing web-brokers would fall within the new proposed definition of web-broker.

Conforming edits are also proposed to § 156.1230 as part of the effort to streamline and consolidate similar requirements that apply to all direct enrollment entities in one regulation. We propose to amend § 156.1230(b) to add a new paragraph (b)(1) that requires issuers participating in direct

enrollment to comply with the applicable requirements in § 155.221. There were minimal substantive changes to the underlying requirements applicable to issuers participating in direct enrollment. We therefore expect no new impact to issuers except to the extent previously discussed. We also propose to delete and reserve § 156.1230(a)(2) to align with the changes, described above, to § 155.415 regarding application assisters.

6. Consumer Assistance Tools and Programs of an Exchange (§ 155.205)

Since implementing the direct-to-issuer enrollment system in plan year 2018, we have seen a marked decrease (greater than fifty percent (50 percent) in SHOP Call Center volume of calls. We anticipate that the SHOP Call Center volume would continue to decrease in plan year 2020, as employers would be in the third year of enrolling with issuers, often with the assistance of agents and brokers. In addition, agents and brokers and small employers can now resolve most issues directly with impacted issuers using well-established issuer call centers and small group processes unique to each market. We would anticipate minimal number of new appeals of SHOP eligibility and SEPs given anticipated employer participation and our observation that very few employers ever appeal SHOP determinations.

In short, we would maintain a toll-free telephone hotline that the statute requires (at present 12 full-time equivalent employees are devoted to SHOP Call Center operations). We envision minimal contractor and staff support to maintain the hotline content and to respond to very few voicemail messages. Although we would maintain language translation service and incur the associated costs, we anticipate that such costs would be minimal given call volume and historical information. Moving to an interactive voice response system would eliminate staffing for 12 full-time equivalent employees required at the call center under the SHOP Plan Aggregate and Call Center contract and would provide a net savings to the government of approximately \$2 million annually.

7. Navigator Program Standards (§§ 155.210 and 155.215)

We propose to provide more flexibility to FFE Navigators by making the provision of certain types of assistance, including post-enrollment assistance, permissible for FFE Navigators, not required. The proposal to amend § 155.210 to remove the requirement that Navigators in FFEs

¹⁶³ Bureau of Labor Statistics mean hourly wage for an Insurance Claims and Policy Processing Clerk (Occupational Code 43-9041) at \$19.76 an hour, plus 100 percent fringe.

provide the assistance specified at § 155.210(e)(9) would reduce regulatory burden and allow FFE Navigators to better prioritize work according to consumer demand, community needs, and organizational resources. Under the proposal, Navigators in FFEs may continue to provide the types of assistance listed at § 155.210(e)(9), but would not be required to do so.

The time FFE Navigators currently spend providing assistance with the § 155.210(e)(9) topics varies. To help quantify this burden reduction, we request comment on how many hours per month FFE Navigator grantees and individual Navigators currently spend providing the assistance activities in § 155.210(e)(9), what percentage of their current work involves providing these types of assistance, and how that amount of work would be impacted if providing these types of assistance would no longer be required. We also request comment on how Navigator grantees and individual Navigators might reprioritize work and spend time fulfilling their other duties, if not required to provide the types of assistance described under § 155.210(e)(9). In particular, we seek comment on what tasks Navigators might prioritize and complete during the time they otherwise might have provided these types of assistance. Examples of how Navigators might elect to reprioritize work and fulfill duties, may include activities such as assisting consumers enroll in health coverage or conducting outreach and education in the community. We anticipate this may include many other activities.

Our proposal to amend Navigator training requirements at § 155.210(b)(2) and § 155.215(b)(2) would provide greater flexibility to Exchanges in designing their Navigator training programs to ensure coverage of the most instructive and timely topics in a streamlined fashion and to align the training with future changes in the Navigator program or the operation of the Exchanges, while still ensuring that Navigators are qualified to carry out their activities as required by the Navigator statute and regulations. This additional flexibility would allow Exchanges to focus on training areas they determine to be most relevant to the populations in the Exchange service area, while still addressing all required or authorized Navigator functions. Because it would provide greater flexibility to tailor the training to current, local conditions in each Exchange, the revised approach might also help to ensure cost-effective use of Exchange Navigator funding.

Moreover, we believe these changes would also grant greater flexibility to SBEs, including SBE-FPs, in designing their respective Navigator training, since under our proposal, SBEs that decide to authorize or require their Navigators to provide the assistance specified under § 155.210(e)(9) would not have corresponding training topics prescribed, but would have the flexibility to decide how best to prepare their Navigators to provide such assistance. This is similar to the flexibility SBEs have for creating training for other required Navigator duties. We believe granting SBEs the flexibility to focus on the topics they find best suited to prepare their Navigators for assisting consumers would allow for a more effective training program, and would reduce the regulatory compliance burden on these Exchanges.

However, the burden reduction that this proposal would achieve cannot be estimated since these changes are not intended to reduce the total number of hours of Navigator training annually and we are uncertain how each Exchange would choose to structure its respective Navigator training given this increase in flexibility. We continue to believe that each Exchange is in the best position to determine the training that is appropriate for the activities of its Navigators.

8. Special Enrollment Periods (§ 155.420)

We anticipate the proposals to amend § 155.420 would impose moderate costs on Exchanges that opt to implement the proposed special enrollment period to update their user interfaces and make changes to their eligibility systems, but also acknowledge that Exchanges may choose to offer the special enrollment period through their call center or other existing enrollment avenues that could greatly reduce implementation costs to an Exchange. Additionally, we anticipate that verification requirements would impose costs relating to special enrollment period pre-enrollment verification systems, caseloads, and consumer messaging for Exchanges that perform pre-enrollment verification of special enrollment period eligibility. We expect utilization of the special enrollment period may vary among Exchanges depending on total Exchange enrollment and Exchange plan rates and pricing practices. Given these variable factors, we are not providing a quantitative cost estimate at this time and request comments regarding anticipated costs, benefits and implementation approaches among

Exchanges to assist in forming a future estimate.

We do not anticipate this proposal would significantly increase regulatory burden on issuers, but acknowledge issuers may encounter marginal costs associated with processing new enrollments and terminations related to the special enrollment period, and direct enrollment entities may also face minor implementation costs associated with updating their applications and systems to include the new special enrollment period. We estimate that it would take a mid-level software developer¹⁶⁴ (at an hourly rate of \$107.48) approximately 10 hours to make the required modifications to the direct enrollment entity's applications and system logic. We estimate a one-time cost burden of approximately \$1,075 per direct enrollment entity. We further estimate a total one-time burden for 35 direct enrollment entities would be approximately 350 hours with an equivalent cost of approximately \$37,618.

Because this policy provides improved pathways to continuous coverage for special enrollment period-eligible consumers, we anticipate that the proposal would promote continuous coverage for consumers and thereby have a positive effect on the individual market risk pool. Additionally, we anticipate that eligible consumers may experience reduced out-of-pocket costs related to health care expenses resulting from access to more affordable health plans and a new pathway to maintaining continuous health care coverage, compared to if they had to drop out of off-Exchange coverage and pay out-of-pocket for all health care expenses incurred for the remainder of the year. We estimate that approximately 4,700 new consumers would use this special enrollment period on an annual basis to enroll in Exchange coverage, and that these consumers would be enrolled in an average of six months of Exchange coverage during the benefit year. Using the plan year 2019 average monthly APTC amount of \$544, we estimate total APTC transferred to consumers as a result of the proposed special enrollment period would be approximately \$15,340,800 annually.¹⁶⁵

We invite comments on the potential costs and savings to Exchanges, issuers,

¹⁶⁴ Bureau of Labor Statistics mean hourly wage for a Software Developer, Systems Software (Occupational Code 15-1133) at \$53.74 an hour, plus 100 percent fringe.

¹⁶⁵ ASPE "2019 Health Plan Choice and Premiums in HealthCare.gov states." <https://aspe.hhs.gov/system/files/pdf/260041/2019LandscapeBrief.pdf>.

direct enrollment entities, and consumers associated with the proposed special enrollment period.

9. Eligibility Standards for Exemptions (§ 155.605)

We do not anticipate that the proposed amendment to § 155.605(e) would create additional costs or burdens on Exchanges, and we anticipate it would decrease burden on consumers. The addition of § 155.605(e)(5) would enable individuals to claim a general hardship exemption on their federal income taxes for 2018 without an exemption certificate number from an Exchange. This policy would allow for more flexibility and would not result in any additional costs or burdens for issuers. The reduction in burden to consumers is discussed previously in the Collection of Information Requirements section.

10. FFE and SBE–FP User Fees (§ 156.50)

To support the operation of FFEs, we require in § 156.50(c) that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through an FFE or SBE–FP. In this proposed rule, for the 2020 benefit year, we propose an FFE user fee rate of 3.0 percent of the monthly premium, and SBE–FP user fee rate of 2.5 percent of the monthly premium. We estimate similar FFE and SBE–FP user fee transfers as those estimated for prior benefit years, and therefore, we are proposing no changes to transfers from issuers to the federal government due to the proposed lower FFE and SBE–FP user fee rates.

11. Prescription Drug Benefit (§ 156.122)

At new § 156.122(d)(3), we propose that for plan years beginning on or after January 1, 2020, QHP issuers in the FFEs would be required to notify HHS annually in an HHS-specified format of any mid-year formulary changes made in the prior plan year consistent with the proposed changes to § 147.106(e). If finalized, we recognize that this proposal would increase issuers' burden due to an additional reporting

requirement. However, we believe that the additional burden would be minimal. Issuers would only be required to submit changes to their formulary, and some issuers may not make changes or may have minimal changes to report. Finally, issuers would only be required to submit formulary changes yearly, and the submission process would be aligned with other submission processes.

12. Prohibition on Discrimination (§ 156.125)

In the preamble to § 156.125, we discuss a potentially discriminatory benefit design under § 156.125: The exclusion of MAT drugs for the treatment of opioid use disorder while covering the same drugs for other medically necessary purposes, such as analgesia or alcohol use disorder. Because we are not proposing a change to policy, we do not anticipate any additional burden on states or issuers. However, to the extent this clarification causes issuers to cease prohibited discriminatory practices, the clarification could help consumers obtain needed MAT, lead to better health outcomes, and reduce the burden and out-of-pocket costs individuals may have otherwise incurred in attempts to obtain MAT.

13. Provisions Related to Cost-Sharing (§ 156.130)

We propose a premium adjustment percentage of 1.2969721275 for the 2020 benefit year, including a proposed change to the premium measure for calculating the premium adjustment percentage. Under § 156.130(e), we propose to use average per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance), instead of employer-sponsored insurance premiums, which were used in the calculation for previous benefit years, for purposes of calculating the premium adjustment percentage for the 2020 benefit year. The annual premium adjustment percentage sets the rate of increase for several parameters detailed in the PPACA, including: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code (defined at § 155.605(d)(2)), and the employer shared responsibility payments under

sections 4980H(a) and 4980H(b) of the Code.

As explained earlier in the preamble, our proposal to use private health insurance premiums (excluding Medigap and property and casualty insurance) in the premium adjustment percentage calculation would result in a faster premium growth rate measure than if we continued to use employer-sponsored insurance premiums as was used for prior benefit years.

To further elaborate on the potential impacts of this proposed policy change, in § 155.605(d)(2), we propose a required contribution of 8.39 percent using the proposed premium adjustment percentage in § 156.130, whereas we would have proposed a required contribution of 8.18 percent if employer-sponsored insurance premiums continued to be used in the premium adjustment percentage calculation for the 2020 benefit year.¹⁶⁶ In § 156.130(a)(2), we propose a maximum annual limitation on cost sharing of \$8,200 for self-only coverage, whereas we would have proposed a maximum annual limitation on cost sharing of \$8,000 for self-only coverage if employer-sponsored insurance premiums continued to be used in the premium adjustment percentage calculation for the 2020 benefit year. The CMS Office of the Actuary estimates that the proposed change in methodology for the calculation of the premium adjustment percentage may have the following impacts between 2019 and 2023:¹⁶⁷

¹⁶⁶ As explained in § 155.605(d)(2), for plan years after 2014, section 5000A(e)(1)(D) of the Code and Treasury regulations at 26 CFR 1.5000A–3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period. Refer to § 155.605(d)(2) for the calculations for the proposed required contribution of 8.39 percent for 2020. To calculate the required contribution we would have proposed of 8.18 percent if employer-sponsored insurance premiums continued to be used in the premium adjustment percentage calculation for the 2020 benefit year, we used employer-sponsored insurance premiums in the calculation: $8.00 * 1.0230638688 (1.2651426338 / 1.2366213610)$, or 8.18 percent.

¹⁶⁷ CMS Office of the Actuary's estimates are based on their health reform model, which is an amalgam of various estimation approaches involving federal programs, employer-sponsored insurance, and individual insurance choice models that ensure consistent estimates of coverage and spending in considering legislative changes to current law.

TABLE 16—IMPACTS OF PROPOSED MODIFICATIONS TO THE 2020 BENEFIT YEAR PREMIUM ADJUSTMENT PERCENTAGE

Calendar year	2019	2020	2021	2022	2023
Exchange Enrollment Impact (enrollees, thousands)	N/A	– 100	– 100	– 100	– 100
Premium Impacts:					
Gross Premium Impact (change from 2018, %)	N/A	0%	0%	0%	0%
Net Premium Impact (change from 2018, %)	N/A	1%	1%	1%	1%
Federal Impacts (dollars, millions):					
Premium Tax Credits (million, \$)	N/A	– 900	– 900	– 1,000	– 1,000
Health Insurance Providers Fee Impact (million, \$)	N/A	0	0	0	100
Employer Shared Responsibility Payment Impact (million, \$)	N/A	100	100	100	100
Total Federal Impact (million, \$)		– 800	– 800	– 900	– 800

As noted in Table 16, we expect that the proposed change in measure of premium growth used to calculate the premium adjustment percentage for the 2020 benefit year may result in:

- Net premium increases of approximately \$181 million per year, which is approximately one percent of 2018 benefit year net premiums, for the 2020 through 2023 benefit years. Net premiums are calculated for Exchange enrollees as premium charged by issuers minus APTC.

- A decrease in federal PTC spending of \$900 million in 2020 and 2021, and \$1 billion in 2022 and 2023, due to an increase in the PTC applicable percentage and a decline in Exchange enrollment of approximately 100,000 individuals in benefit year 2020, based on an assumption that the Department of the Treasury and the IRS will adopt the use of the same premium measure proposed for the calculation of the premium adjustment percentage in this rule for purposes of calculating the indexing of the PTC applicable percentage and the required contribution percentage under section 36B of the Code. We anticipate that enrollment may decline by 100,000 individuals in benefit year 2020, and enrollment would remain lower by 100,000 individuals in each year between 2020 and 2023 than it would if there were no proposed change in premium measure for the premium adjustment percentage for the 2020 benefit year.

- Increased Health Insurance Providers Fees on health insurance issuers of approximately \$100 million in 2023, based on an assumption that the Department of the Treasury and the IRS would adopt the use of the same premium measure proposed for the calculation of the premium adjustment percentage in this rule for purposes of calculating the indexing of the Health Insurance Providers Fee. We anticipate that the Health Insurance Providers Fee would initially not be noticeably

affected, but would increase in 2023 and beyond due to the cumulative indexing effect.

- Increased Employer Shared Responsibility Payments of \$100 million each year between 2020 and 2023.

Some of the 100,000 individuals estimated to not enroll in Exchange coverage as a result of the proposed change in the measure of premium growth used to calculate the premium adjustment percentage may purchase short-term, limited-duration insurance, though a majority is likely to become uninsured. Either transition may result in greater exposure to health care costs, which previous research suggests reduces utilization of health care services.¹⁶⁸ Economic distortions may be reduced, and economic efficiency and social benefits improved, because these individuals will be bearing a larger share of the costs of their own health care consumption, potentially reducing spending on health care services that are personally only marginally valued but that imposes costs on the federal government through subsidies. In addition, to the extent that this proposed rule reduces federal outlays and thereby reduces the need to collect taxes in the future, the distortionary effects of taxation on the economy may be reduced. However, the increased number of uninsured may increase federal and state uncompensated care costs. We seek feedback from stakeholders about these impacts and the magnitude of these changes.

As noted above, the premium adjustment percentage is the measure of

¹⁶⁸ Manning, W. G., Newhouse, J. P., Duan, N., Keeler, E. B., & Leibowitz, A. (1987). Health insurance and the demand for medical care: evidence from a randomized experiment. *The American economic review*, 251–277; Keeler, E. B., & Rolph, J. E. (1988). The demand for episodes of treatment in the health insurance experiment. *Journal of health economics*, 7(4), 337–367; Finkelstein, A., et al. (2012). The Oregon health insurance experiment: evidence from the first year. *The Quarterly journal of economics*, 127(3), 1057–1106.

premium growth that is used to set the rate of increase for the maximum annual limitation on cost sharing, defined at § 156.130(a). In § 156.130(a)(2), we propose a maximum annual limitation on cost sharing of \$8,200 for self-only coverage. Additionally, we propose reductions in the maximum annual limitation on cost sharing for silver plan variations. Consistent with our analyses in previous Payment Notices, we developed three test silver level QHPs and analyzed the impact on their AVs of the reductions described in the PPACA to the estimated 2020 maximum annual limitation on cost sharing for self-only coverage. We do not believe the proposed changes to the reductions in the maximum annual limitation on cost sharing for silver plan variations would result in a significant economic impact.

We propose two new policies at § 156.130(h) which aim to reduce costs associated with coverage of in prescription drugs by giving health insurance issuers more flexibility in changing how drugs costs are counted toward the annual limitation on cost sharing. According to our research, we believe these new flexibilities will allow health insurance issuers to reduce premiums between 1.5 percent and 3 percent of drug spending with moderate variation by plan type, geography, or metal level. These estimates reflect an impact separate from the quantitative estimates above.

14. Provisions Related to Abortion Services (§ 156.280)

In § 156.280(c)(3), we propose that, beginning with plan year 2020, QHP issuers that provide coverage of non-Hyde abortion services in one or more QHPs at any metal level in a particular service area must also provide at least one “mirror QHP” throughout that service area that provides otherwise identical benefits as one of the QHPs with non-Hyde abortion coverage, but that omits coverage of such services. This requirement would apply to the

extent permitted by state law. To date, QHP issuers have not been required to offer such a plan.

Based on 2018 QHP certification data in FFEs and SBE-FPs, we estimate that 15 issuers offered a total of 111 plans with coverage of non-Hyde abortion services in 7 states. In SBEs we estimate that 60 QHP issuers offered a total of approximately 1,000 plans offering non-Hyde abortion coverage across 10 SBEs. In total, this leads to an estimate of 75 QHP issuers offering a total of 1,111 plans covering non-Hyde abortion services across 17 states. Requiring issuers to offer mirror QHPs would require issuers offering coverage for non-Hyde abortion services to create at least one additional QHP that does not offer coverage for such services throughout each of their service areas in the Exchange where they offer QHPs covering non-Hyde abortion services. We believe that the proposal would attract potential customers who may find the benefits offered under the QHP attractive, but would not, on conscience grounds, purchase a QHP that includes coverage of non-Hyde abortion services.

However, we recognize that issuers may find this proposal unfavorable because of the increase in burden to develop and review additional plans, including additional resources to create additional plan designs and administer additional plans.¹⁶⁹ Due to the increased burden this proposed policy change may place on issuers, some issuers may choose to not offer non-Hyde abortion coverage at all as part of their benefit package (rather than offer mirror QHPs). If issuers choose to not offer non-Hyde abortion coverage, this may lead to an increase in women who lack options for enrolling in plans that offer coverage for non-Hyde abortion, thus requiring more women to pay out-of-pocket for these services, if they become pregnant and choose to have an abortion. The cost of abortion services without insurance coverage is dependent on a variety of factors, such as location, type of medical facility, timing of the procedure, and type of procedure.

If finalized, this proposal would also increase the burden on states operating

their own Exchange by requiring that they conduct additional QHP reviews, approve additional products, and review additional rate and policy forms.¹⁷⁰ This proposal would increase the number of benefit reviews states would have to conduct for these plans as a part of the QHP certification process, depending on the number of mirror QHPs without non-Hyde abortion coverage the QHP issuers opt to offer. However, state law on abortion coverage significantly shapes and limits the availability of abortion coverage on the Exchanges. Although many states have enacted laws more restrictive than the federal requirements in section 1303 of the PPACA,¹⁷¹ other states have laws requiring QHPs to offer abortion coverage on the Exchange. For example, California and New York currently require QHPs to offer abortion coverage on the Exchange.¹⁷² Oregon recently signed into law a requirement for QHPs to include coverage for abortion, effective for 2019.¹⁷³ Therefore, the impact would depend on the applicable state law.¹⁷⁴

Finally, we believe that the proposed requirement would increase consumer choice by offering additional plan options to potential enrollees who may refuse to enroll in, or may be discouraged from enrolling in QHPs because the plans in their service area

¹⁷⁰ See also n. 158, *supra*.

¹⁷¹ Some state laws prohibit QHPs from offering any abortion coverage on the Exchange, even in cases where the Hyde Amendment would permit federal funding to be used for such coverage; others prohibit all private insurers in the state from offering abortion coverage, regardless of whether the plan is offered on the Exchange; and many limit on-Exchange QHPs to only offering Hyde-abortion coverage.

¹⁷² California requires all insurance carriers (except for multi-state plans) to cover non-Hyde abortion. See Michelle Rouillard, Director of Department of Managed Health Care letter to Mark Morgan, California President of Anthem Blue Cross, RE: Limitations or Exclusions of Abortion Services (August 22, 2014). Available at <https://www.dnhc.ca.gov/Portals/0/082214letters/abc082214.pdf>. Also see Cal. Health & Safety Code § 1340 *et seq.* New York requires all insurance policies that provide hospital, surgical, or medical expense coverage to also include coverage for abortions that are medically necessary. See N.Y. Ins. Law § 3217 (2015); N.Y. Comp. Codes R. & Regs. tit. 11, § 52.2 (2016).

¹⁷³ The Oregon law requires all health insurance plans in the state to cover non-Hyde abortions with no out-of-pocket costs. See <https://olis.leg.state.or.us/liz/2017R1/Downloads/MeasureDocument/HB3391/Enrolled>.

¹⁷⁴ As of 2014, there were 23 states with laws restricting the circumstances under which QHPs could offer non-Hyde abortion services as a covered benefit. Twenty-eight states had no laws restricting the circumstances under which QHPs could offer non-Hyde abortion services. In 5 states (Connecticut, Hawaii, New Jersey, Rhode Island, and Vermont) all QHPs covered non-Hyde abortion services. <https://www.gao.gov/assets/670/665800.pdf>.

cover non-Hyde abortion services. We realize that but for the premium and benefit description, the QHPs would otherwise appear identical, and are concerned that consumers who do not carefully study their plan options may be confused by the premium differential; accordingly, we request comment on appropriate measures or requirements to limit the possibility of such confusion. Research has shown that offering consumers additional health plan options may result in consumers opting to not purchase a plan at all.

We seek comment on the overall impact of the proposal.

15. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We are required to issue a substantial portion of this rule each year under our regulations and we estimate that approximately half of the remaining provisions would cause additional regulatory review burden that stakeholders do not already anticipate. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule, excluding the portion of the rule that we are required to issue each year.

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 \$107.38 per hour, including overhead

¹⁶⁹ We note, however, that the proposal is to require at least one mirror QHP throughout each service area in which the QHP issuer offers plans covering non-Hyde abortion, that provides otherwise identical benefits as one of the QHPs with non-Hyde abortion coverage, but that omits coverage of such services. As such, issuers with QHPs that cover non-Hyde abortion would already have developed the basic plan design and structure of the mirror QHP, and we believe this will significantly aid issuers in filling out and reviewing the additional rate and policy forms for the mirror plan.

and fringe benefits.¹⁷⁵ Assuming an average reading speed, we estimate that it would take approximately 1 hour for the staff to review the relevant portions of this proposed rule that causes unanticipated burden. We assume that 321 entities will review this proposed rule. For each entity that reviews the rule, the estimated a cost of approximately \$107.38. Therefore, we estimate that the total cost of reviewing this regulation is approximately \$34,469 (\$107.38 × 321 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this proposed rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

At § 147.106 we propose to allow issuers to make certain mid-year formulary changes in an effort to optimize the use of new generic drugs as they become available. We recognize that the question of whether incentivizing the use of generic drugs will result in lowered costs is a complex question given certain dynamics in the drug market, such as rebates, and we, therefore, considered not proposing these changes. However, we believe that allowing issuers to make mid-year formulary changes or the option to direct consumers to generic drugs over the branded drug will result in a reduction in prescription drug costs.

In proposing the risk adjustment model recalibration in part 153, we considered multiple alternatives such as maintaining the prior year's recalibration methodology of recalibrating the models using 2 years of MarketScan® data and the most recent year of EDGE data. However, while we are maintaining our approach of recalibrating the models using 3 years of blended data, we are proposing to use to the 2 most recent years of enrollee-level EDGE data (2016 and 2017) and the most recent year for MarketScan® data (2017) available. We believe that this approach will better reflect the experience of issuers in the individual and small group markets by using the most recent claims data available.

We considered updating the induced demand factors (IDFs) in the risk adjustment state payment transfer formula and the cost-sharing reduction adjustment factors using results from 2016 enrollee-level EDGE data to evaluate the differences in enrollee spending patterns. However, although we have begun our analysis of 2016 enrollee-level EDGE data to evaluate

differences in induced demand, we are not proposing any changes to the existing IDFs for the 2020 benefit year with the intention of evaluating additional data before proposing to make any changes. We intend to consider amending IDFs for the 2021 benefit year when we can also evaluate 2017 enrollee-level EDGE data to examine differences in induced demand by market.

Beginning with the 2019 benefit year of risk adjustment data validation,¹⁷⁶ we propose to vary the initial validation audit sample size, and outline several different approaches we are considering for doing so. For example, we could vary sample size based on HCC failure rates, sample precision, and issuer size. An alternative approach would vary the initial validation audit sample size based only on issuer size. We also solicit comment on whether to permit issuers of any size and with any HCC failure rate the flexibility to request a larger sample size. Larger initial validation audit sample sizes could be required for some issuers under these approaches; however, we believe any increased burden would be outweighed by the increased precision of the risk adjustment data validation results which are used to adjust issuers risk scores and associated risk adjustment transfers.

Regarding proposed changes to §§ 155.210 and 155.215, we considered taking no action to amend certain Navigator training requirements and duties, but determined that the proposed changes regarding training requirements would provide Exchanges with needed flexibility, and the proposed changes regarding duties of FFE Navigators would help reduce burden on FFE Navigators.

After several years of agent, broker and web-broker participation in the FFEs, we have identified key differences between individual agents or brokers and agent or broker entities, and believe these differences warrant a more tailored approach to regulating agents, brokers and web-brokers. For example, we believe the requirement for an agent, broker or web-broker entity to complete FFE training imposes a regulatory burden with little benefit, because entities are businesses employing or contracting with many individuals, many of whom are licensed agents or brokers who have to take the FFE training as part of their respective FFE registration as individuals. Instead of continuing to require these entities to

identify an individual agent or broker to complete training on their behalf, we propose to eliminate a separate training requirement for agent, broker or web-broker entities. All individual agents and brokers assisting Exchange consumers in the individual market, whether or not they are assisting consumers in partnership with an agent, broker or web-broker entity, would continue to be required to receive training as part of the annual FFE registration process. Similarly, because of the different characteristics of individual agents or brokers and web-brokers, we propose to include provisions specifically related to suspension and termination of a web-broker's agreement that are inapplicable to individual agents or brokers but that generally mirror the standards and existing procedures for suspension or termination of an individual agent's or broker's agreement(s).

In proposing revisions to § 155.221, we considered maintaining the existing regulatory framework that established standards for issuers and web-brokers participating in direct enrollment in separate sections, but we believe streamlining and consolidating the requirements applicable to all direct enrollment entities, when possible, improves clarity and promotes fair competition. In proposing the display requirements at § 155.221(b), we contemplated maintaining the current standards in regulations and guidance, but based on feedback received from direct enrollment entities, we believe the current framework has caused confusion and limited innovation. Therefore, we determined that the establishment of clarified standards for the marketing and display of QHPs and non-QHPs is the best way to provide greater clarity for direct enrollment entities about what is required to minimize the potential for consumer confusion while allowing direct enrollment entities more flexibility to be innovative in the marketing of non-QHPs to consumers who are interested in those products. In proposing the addition of a new § 155.221(c), we considered continuing to limit the authority to use application assisters to QHP issuers. However, to promote fair competition for all direct enrollment entities and issuers, we believe a better approach is to expand this authority to include all direct enrollment entities and all issuers.

We considered broader eligibility requirements for the special enrollment period proposed at § 155.420(d)(6)(v). We considered if a special enrollment period could be offered without a decrease in household income to all

¹⁷⁶ Activities related to the 2019 benefit year risk adjustment data validation generally begin in the second quarter of the 2020 calendar year.

¹⁷⁵ https://www.bls.gov/oes/current/oes_nat.htm.

Exchange applicants who were enrolled in MEC and determined eligible for APTC by the Exchange, or if changes in the applicant's household size could be considered in the eligibility criteria for this special enrollment period. We determined that eliminating the criteria for a decrease in household income would be problematic because it eliminates a triggering event for the special enrollment period and could allow for consumers who are potentially APTC-eligible to avoid the metal level restrictions in paragraph (a)(4) of this section by initially enrolling in off-Exchange coverage and then later choosing to buy a higher or lower level of coverage mid-year. We also determined that verification of household size changes would be operationally problematic, as electronic data sources would not reflect recent changes to household size. Further, the special enrollment periods at § 155.420(d)(2)(i) are currently available to qualified individuals whose household size changes due to gaining or becoming a dependent and already provides a pathway to Exchange coverage for individuals in this situation. We also considered if the special enrollment period could be offered without a prior coverage requirement and determined that this requirement is necessary to ensure the special enrollment period is only available to the intended population, to promote continuous coverage among individual market enrollees, and to protect the Exchanges against adverse selection. Finally we considered the impact of not proposing this special enrollment period. Without the proposed special enrollment period at § 155.420(d)(6)(v), unsubsidized consumers who experience a decrease in household income midyear and are APTC eligible would remain without a pathway to Exchange coverage. These consumers would remain at risk of terminating their unsubsidized coverage midyear because it is unaffordable, rather than maintaining continuous enrollment in health coverage by transitioning to an Exchange plan.

Without the recommended revisions to § 155.605(e), individuals may experience a general hardship that prevents them from obtaining qualifying health coverage, and may experience undue burden to apply and qualify for an exemption from the individual shared responsibility provision to purchase qualifying health coverage. This change allows for more flexibility for individuals to claim these exemptions through the IRS tax filing process for 2018.

In proposing the change to the premium measure used in the premium adjustment percentage calculation under § 156.130, we considered continuing to use the current premium measure, as well as other premium measures for purposes of calculating the premium adjustment percentage for the 2020 benefit year. We considered continuing to use the current premium measure, NHEA's estimates and projections of average per enrollee employer-sponsored insurance premiums. We are proposing a change to this measure to instead use a private health insurance premium measure (excluding Medigap and property and casualty insurance), so that the premium growth measure more closely reflects premium trends in the private health insurance market since 2013. Alternatively, we considered using NHEA estimates and projections of average per enrollee private health insurance premiums. NHEA's private health insurance premium measure includes premiums for employer-sponsored insurance, direct purchase insurance (which includes Medigap insurance), and property and casualty insurance. However, we propose to include only those premiums for expenditures associated with the acquisition of one's primary health insurance coverage purchased through their employer or purchased directly from a health insurance issuer. We believe it is inappropriate to include Medigap premiums in the measure as this type of coverage is not considered primary coverage for those enrollees who supplement their Medicare coverage with these plans. Moreover, although total spending for private health insurance in the NHEAs includes the medical portion of accident insurance (property and casualty insurance), we do not believe it would be appropriate to include those expenditures for this purpose as they are associated with policies that do not serve as a primary source of health insurance coverage.

Accordingly, in § 156.130 we propose using a measure that includes only premiums for employer-sponsored insurance and direct purchase insurance, but not premiums for property and casualty, or Medigap insurance. In addition to considering NHEA's private health insurance premiums as an alternative for measuring premium growth in the premium adjustment percentage calculation, we considered using Exchange premiums as the measure for premium growth. However, a significant drawback with using Exchange

premiums is that the Exchanges did not exist in 2013 and therefore Exchange premiums are not available for 2013. NHEA does not currently publish projections of Exchange premiums separate from the estimates and projections that they include within the direct purchase premium measure, and a projection would be needed for the 2019 premium amount given the timing of this proposed rule and the estimated timing of the final HHS Notice of Benefit and Payment Parameters for 2020 rule. We seek comment on the source of premium data we use in the premium adjustment percentage calculation, and specifically the proposal to use average per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance) or whether we continue to use employer-sponsored insurance premiums for purposes of calculating the premium adjustment percentage for the 2020 benefit year.

At § 156.130 we also propose that plans are not required to count drug manufacturer coupons toward the annual limitation on cost sharing, starting with plan years beginning on or after January 1, 2020. We considered not proposing this flexibility, as these coupons may result in lower costs to individual consumers. However, manufacturer coupons may incentivize selection of higher-cost drugs when a less costly therapeutic equivalent is available which can distort the market and the true costs of drugs, adding significant long-term costs to the health care system.

In proposing § 156.280(c)(3), we considered whether regulatory action was necessary at all. However, without regulatory action, some people may not be able to enroll in what would otherwise be their desired QHP, but for the QHP covering non-Hyde abortion, due to religious or conscience objections. This proposal would allow people who do not desire coverage of non-Hyde abortion to have coverage alternatives. We also considered requiring issuers to offer QHPs that do not cover non-Hyde abortion services on a one-to-one basis with QHPs that do cover non-Hyde abortion services. However, we were concerned that this would be too burdensome to QHP issuers and that a proliferation of so many more QHPs could be confusing to consumers.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act, (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless

the head of the agency can certify that the rule will not have a significant economic 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 not-for-profit 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.” HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this proposed rule, we propose standards for the risk adjustment and risk adjustment data validation programs, which are intended to stabilize premiums as insurance market reforms are implemented and Exchanges facilitate increased enrollment. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for “small entities” established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$38.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be \$32.5 million or less.¹⁷⁷ We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report¹⁷⁸ submissions for the 2016 MLR reporting year, approximately 85 out of over 520 issuers of health insurance coverage nationwide had total premium revenue of \$38.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since almost 79 percent of these small companies belong to larger

holding groups, and many if not all of these small companies are likely to have non-health lines of business that will result in their revenues exceeding \$38.5 million.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis 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 of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would not affect small rural hospitals. Therefore, the Secretary has determined that this will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has Federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the states, we have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis.

While developing this rule, we attempted to balance the states’ interests in regulating health insurance issuers with the need to ensure market stability. By doing so, it is our view that we have

complied with the requirements of Executive Order 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For states that elected previously to operate an Exchange, or risk adjustment program, much of the initial cost of creating these programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the state. Current State Exchanges charge user fees to issuers.

In our view, while this proposed rule would not impose substantial direct requirement costs on state and local governments, this regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. For example, for risk adjustment, we are proposing more flexibility for states that want to use something other than statewide average premium in the calculation of transfers. We are also proposing to make the proposed special enrollment period at § 155.420(d)(6)(v) at the option of Exchanges, to give states flexibility in whether they choose to implement it.

H. Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to the Congress and the Comptroller for review.

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of

¹⁷⁷ <https://www.sba.gov/document/support-table-size-standards>.

¹⁷⁸ Available at <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

The designation of this rule, if finalized, will be informed by public comments received.

J. Conclusion

The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Insurance companies, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 153

Administrative practice and procedure, Health care, Health insurance, Health records, Intergovernmental relations, Organization and functions (Government agencies), Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

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, under the authority at 5 U.S.C. 301, the Department of Health and Human Services proposes to amend 45 CFR as set forth below.

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 1. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92.

■ 2. Section 146.152 is amended by revising paragraphs (a) and (f)(1) introductory text and adding paragraph (f)(5) to read as follows:

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

(a) *General rule.* Subject to paragraphs (b) through (f) of this section, a health insurance issuer offering health insurance coverage in the small or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

* * * * *

(f) * * *

(1) Subject to paragraph (f)(5) of this section, only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan, in the following:

* * * * *

(5) For plan years beginning on or after January 1, 2020, a group health insurance issuer may make the following mid-year formulary changes, to the extent permitted by applicable State law: It may add a generic equivalent to a formulary within a reasonable time after the generic equivalent becomes available, and, if it does so, it may remove the equivalent brand drug or drugs from the formulary or move the equivalent brand drug or drugs to a higher formulary drug tier. If the issuer makes any such changes:

(i) The issuer must notify plan enrollees in writing a minimum of 60 days prior to making the changes. This notice must identify the name of the

brand drug that is the subject of the change, disclose whether the brand drug will be removed from the formulary or placed on a different cost-sharing tier, provide the name of the generic equivalent that will be made available, specify the date the changes will become effective, and state that under the appeals processes outlined in § 147.136 of this subchapter or the exceptions processes outlined in § 156.122(c) of this subchapter, enrollees and dependents may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan.

(ii) The mid-year formulary changes must not exceed the scope of a uniform modification as defined in this paragraph (f).

(iii) All plan enrollees must have access to the applicable coverage appeal process under § 147.136 of this subchapter or the drug exception request process under § 156.122(c) of this subchapter to request access to the equivalent brand drug or drugs.

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 3. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

■ 4. Section 147.106 is amended by revising paragraphs (a) and (e)(1) introductory text and adding paragraph (e)(5) to read as follows:

§ 147.106 Guaranteed renewability of coverage.

(a) *General rule.* Subject to paragraphs (b) through (e) of this section, a health insurance issuer offering health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

* * * * *

(e) * * *

(1) Subject to paragraph (e)(5) of this section, only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan or an individual, as applicable, in the following:

* * * * *

(5) For plan years beginning on or after January 1, 2020, a health insurance issuer may make the following mid-year formulary changes, to the extent permitted by applicable State law: It may add a generic equivalent to a

formulary within a reasonable time after the generic equivalent becomes available, and, if it does so, it may remove the equivalent brand drug or drugs from the formulary or move the equivalent brand drug or drugs to a higher formulary drug tier. If the issuer makes any such changes:

(i) The issuer must notify plan enrollees in writing a minimum of 60 days prior to making the changes. This notice must identify the name of the brand drug that is the subject of the change, disclose whether the brand drug will be removed from the formulary or placed on a different cost-sharing tier, provide the name of the generic equivalent that will be made available, specify the date the changes will become effective, and state that under the appeals processes outlined in § 147.136 of this subchapter or the exceptions processes outlined in § 156.122(c) of this subchapter, enrollees and dependents may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan.

(ii) The mid-year formulary changes must not exceed the scope of a uniform modification as defined in this paragraph (e).

(iii) All plan enrollees must have access to the applicable coverage appeal process under § 147.136 of this subchapter or the drug exception request process under § 156.122(c) of this subchapter to request access to the equivalent brand drug or drugs.

* * * * *

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 5. The authority citation for part 148 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg-63, 300gg-11 300gg-91, and 300gg-92, as amended.

■ 6. Section 148.122 is amended by revising paragraphs (b)(1) and (g)(1) and adding paragraph (g)(5) to read as follows:

§ 148.122 Guaranteed renewability of individual health insurance coverage.

* * * * *

(b) * * *

(1) Except as provided in paragraphs (c) through (g) of this section, an issuer must renew or continue in force the coverage at the option of the individual.

* * * * *

(g) * * *

(1) Subject to paragraph (g)(5) of this section, an issuer may, only at the time of coverage renewal, modify the health insurance coverage for a product offered

in the individual market if the modification is consistent with State law and is effective uniformly for all individuals with that product.

* * * * *

(5) For plan years beginning on or after January 1, 2020, an individual market health insurance issuer may make the following mid-year formulary changes, to the extent permitted by applicable State law: It may add a generic equivalent to a formulary within a reasonable time after the generic equivalent becomes available, and, if it does so, it may remove the equivalent brand drug or drugs from the formulary or move the equivalent brand drug or drugs to a higher formulary drug tier. If the issuer makes any such changes:

(i) The issuer must notify plan enrollees in writing a minimum of 60 days prior to making the changes. This notice must identify the name of the brand drug that is the subject of the change, disclose whether the brand drug will be removed from the formulary or placed on a different cost-sharing tier, provide the name of the generic equivalent that will be made available, specify the date the changes will become effective, and state that under the appeals processes outlined in § 147.136 of this subchapter or the exceptions processes outlined in § 156.122(c) of this subchapter, enrollees and dependents may request and gain access to the brand drug when clinically appropriate and not otherwise covered by the health plan.

(ii) The mid-year formulary changes must not exceed the scope of a uniform modification as defined in this paragraph (g).

(iii) All plan enrollees must have access to the applicable coverage appeal process under § 147.136 of this subchapter or the drug exception request process under § 156.122(c) of this subchapter to request access to the equivalent brand drug or drugs.

* * * * *

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

■ 7. The authority citation for part 153 is revised to read as follows:

Authority: 42 U.S.C. 18031, 18041, and 18061 through 18063.

■ 8. Section 153.320 is amended by revising paragraph (d)(3) to read as follows:

§ 153.320 Federally certified risk adjustment methodology.

* * * * *

(d) * * *

(3) *Publication of Reduction Requests.* HHS will publish State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters proposed rule and make the supporting evidence available to the public for comment, except to the extent the State requests HHS not publish certain supporting evidence because it contains trade secrets or confidential commercial or financial information as defined in HHS's Freedom of Information regulations under 45 CFR 5.31(d). HHS will publish any approved State reduction requests or denied State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters final rule.

* * * * *

■ 9. Section 153.630 is amended by revising paragraphs (b)(10) and (d)(2) and adding paragraph (g) to read as follows:

§ 153.630 Data validation requirements when HHS operates risk adjustment.

* * * * *

(b) * * *

(10) If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS will impose a default data validation charge.

* * * * *

(d) * * *

(2) Within 15 calendar days of the notification by HHS of the findings of a second validation audit (if applicable) or the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the findings of the second validation audit (if applicable) or the calculation of the risk score error rate as a result of risk adjustment data validation, or file a discrepancy report to dispute the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as a result of risk adjustment data validation.

* * * * *

(g) *Exemptions.* An issuer of a risk adjustment covered plan will be exempted by HHS from the data validation requirement set forth in paragraph (b) of this section for a given benefit year if:

(1) The issuer has 500 or fewer billable member months of enrollment in the individual, small group and merged markets (as applicable) for the applicable benefit year, calculated on a Statewide basis beginning with the 2017 benefit year of risk adjustment data validation;

(2) The issuer is at or below the materiality threshold as defined by HHS

and is not selected by HHS to participate in the data validation requirements in an applicable benefit year under random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers based on experience that would warrant more frequent audits) beginning with the 2018 benefit year of risk adjustment data validation; or

(3) The issuer is in liquidation, or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited, provided that:

(i) Beginning with the 2017 benefit year and beyond, the issuer provides to HHS, in the manner and timeframe specified by HHS, an attestation that the issuer is in liquidation or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited that is signed by an individual with the authority to legally and financially bind the issuer; and

(ii) Beginning with the 2018 benefit year and beyond, the issuer is not a positive error rate outlier under the error estimation methodology in risk adjustment data validation for the prior benefit year of risk adjustment data validation.

(iii) For purposes of this paragraph (g)(3), liquidation means that a State court has issued an order of liquidation for the issuer that fixes the rights and liabilities of the issuer and its creditors, policyholders, shareholders, members, and all other persons of interest.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 10. The authority citation for part 155 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 11. Section 155.20 is amended by adding in alphabetical order definitions for “Direct enrollment entity,” “Direct enrollment entity application assister,” “Direct enrollment technology provider,” and “Web-broker” to read as follows:

§ 155.20 Definitions.

* * * * *

Direct enrollment entity means an entity that an Exchange permits to assist consumers with direct enrollment in qualified health plans offered through the Exchange in a manner considered to be through the Exchange as authorized by § 155.220(c)(3), § 155.221, or § 156.1230 of this subchapter.

Direct enrollment entity application assister means an employee, contractor, or agent of a direct enrollment entity who is not licensed as an agent, broker, or producer under State law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs.

Direct enrollment technology provider means a type of web-broker business entity that is not a licensed agent, broker, or producer under State law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221.

* * * * *

Web-broker means an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under § 155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in qualified health plans offered through the Exchange as described in §§ 155.220(c)(3) and 155.221. The term also includes a direct enrollment technology provider.

■ 12. Section 155.205 is amended by revising paragraph (a) to read as follows:

§ 155.205 Consumer assistance tools and programs of an Exchange.

(a) *Call center.* The Exchange must provide for operation of a toll-free call center that addresses the needs of consumers requesting assistance and meets the requirements outlined in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section, unless it is an Exchange described in paragraphs (a)(1) or (2) of this section, in which case, the Exchange must provide at a minimum a toll-free telephone hotline that includes the capability to provide information to consumers about eligibility and enrollment processes, and to appropriately direct consumers to the applicable Exchange website and other applicable resources.

(1) An Exchange described in this paragraph is one that enters into a Federal platform agreement through which it relies on HHS to operate its eligibility and enrollment functions, as applicable.

(2) An Exchange described in this paragraph is a SHOP that does not provide for enrollment in SHOP coverage through an online SHOP enrollment platform, but rather provides for enrollment through SHOP issuers or

agents and brokers registered with the Exchange.

* * * * *

■ 13. Section 155.210 is amended by:

■ a. Revising paragraph (b)(2) introductory text and paragraphs (b)(2)(iii) and (iv);

■ b. Removing paragraphs (b)(2)(v) through (ix); and

■ c. Revising the paragraph (e)(9) introductory text.

The revisions read as follows:

§ 155.210 Navigator program standards.

* * * * *

(b) * * *

(2) A set of training standards, to be met by all entities and individuals carrying out Navigator functions under the terms of a Navigator grant, to ensure the entities and individuals are qualified to engage in Navigator activities, including training standards on the following topics:

* * * * *

(iii) The range of QHP options and insurance affordability programs; and

(iv) The privacy and security standards applicable under § 155.260.

* * * * *

(e) * * *

(9) The Exchange may require or authorize Navigators to provide information and assistance with any of the following topics. In Federally-facilitated Exchanges, Navigators are required to provide information and assistance with all of the following topics under Navigator grants awarded in 2018, and will be authorized to provide information and assistance with all of the following topics under Navigator grants awarded in 2019 or any later year.

* * * * *

■ 14. Section 155.215 is amended by revising paragraph (b)(2) to read as follows:

§ 155.215 Standards applicable to Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to Non-Navigator Assistance Personnel funded through an Exchange Establishment Grant.

* * * * *

(b) * * *

(2) *Training module content standards.* All individuals who carry out the consumer assistance functions under §§ 155.205(d) and (e) and 155.210 of this subpart must receive training consistent with standards established by the Exchange consistent with § 155.210(b)(2) of this subpart.

* * * * *

■ 15. Section 155.220 is amended by:

- a. Revising the section heading;
- b. Revising paragraphs (a) introductory text, (c) introductory text, (c)(1), (c)(3)(i) introductory text and (c)(3)(i)(A), (D), (K) and (L), (c)(3)(ii) introductory text, (c)(4) introductory text, (c)(4)(i) introductory text, (c)(4)(i)(A), (E) and (F), (c)(4)(ii), (c)(5), (d) introductory text, (d)(2), (e), (f)(1) and (2), (f)(3) introductory text, (f)(3)(i), (f)(4), (g)(1), (g)(2) introductory text, (g)(3) and (4), (g)(5)(i) through (iii), (h), (i), (j)(1) introductory text, (j)(3), (k)(1) introductory text, and (k)(2);
- c. Adding paragraph (k)(3);
- d. Revising paragraph (l); and
- e. Adding paragraph (m).

The additions and revisions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

(a) *General rule.* A State may permit agents, brokers, and web-brokers to—

* * * * *

(c) *Enrollment through the Exchange.* A qualified individual may be enrolled in a QHP through the Exchange with the assistance of an agent, broker, or web-broker if—

(1) The agent, broker, or web-broker ensures the applicant's completion of an eligibility verification and enrollment application through the Exchange internet website as described in § 155.405, or ensures that the eligibility application information is submitted for an eligibility determination through the Exchange-approved web service subject to meeting the requirements in paragraphs (c)(3)(ii) and (c)(4)(i)(F) of this section;

* * * * *

(3)(i) When an internet website of a web-broker is used to complete the QHP selection, at a minimum the internet website must:

(A) Disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of § 155.205(b)(1) and (c), and to the extent that not all information required under § 155.205(b)(1) is displayed on the web-broker's internet website for a QHP, prominently display a standardized disclaimer provided by HHS stating that information required under § 155.205(b)(1) for the QHP is available on the Exchange website, and provide a Web link to the Exchange website;

* * * * *

(D) When permitted under state law, Navigators and certified application counselors may use the website of a web-broker while assisting an applicant

to enroll in a QHP offered through the Exchange if:

(1) The website displays all QHP data provided by the Exchange consistent with the requirements of § 155.205(b)(1) and (c), and to the extent the web-broker website does not facilitate enrollment in all QHPs offered through the Exchange, identifies such QHPs (if any) to consumers by prominently displaying a standardized disclaimer provided by the Exchange, in a manner and form specified by the Exchange, stating that enrollment in such QHPs can be completed through the Exchange website and providing a link to the Exchange website; and

(2) The web-broker who makes its website available may complete an annual certification process with the Exchange, in the manner and form specified by the Exchange, by attesting to its compliance with the requirements in paragraph (c)(3)(i)(D)(1) of this section;

* * * * *

(K) Comply with the applicable requirements in § 155.221; and

(L) Not display QHP recommendations based on compensation the agent, broker, or web-broker receives from QHP issuers.

(ii) When an internet website of a web-broker is used to complete the Exchange eligibility application, at a minimum the internet website must:

* * * * *

(4) When an agent or broker, through a contract or other arrangement, uses the internet website of a web-broker to help an applicant or enrollee complete a QHP selection or complete the Exchange eligibility application in the Federally-facilitated Exchange:

(i) The web-broker who makes the website available must:

(A) Provide HHS with a list of agents and brokers who enter into such a contract or other arrangement to use the web-broker's website, in a form and manner to be specified by HHS;

* * * * *

(E) Report to HHS and applicable State departments of insurance any potential material breach of the standards in paragraphs (c) and (d) of this section, or the agreement entered into under § 155.260(b), by the agent or broker accessing the internet website, should it become aware of any such potential breach. A web-broker that provides access to its website to complete the QHP selection or the Exchange eligibility application or ability to transact information with HHS to another web-broker website is responsible for ensuring compliance with applicable requirements in

paragraph (c)(3) of this section for any web pages of the other web-broker's website that assist consumers, applicants, qualified individuals, and enrollees in applying for APTC and CSRs for QHPs, or in completing enrollment in QHPs, offered in the Exchanges.

(F) When an internet website of a web-broker is used to complete the Exchange eligibility application, obtain HHS approval verifying that all requirements in this section are met.

(ii) HHS retains the right to temporarily suspend the ability of the web-broker making its website available to transact information with HHS, if HHS discovers a security and privacy incident or breach, for the period in which HHS begins to conduct an investigation and until the incident or breach is remedied to HHS's satisfaction.

(5) HHS or its designee may periodically monitor and audit an agent, broker, or web-broker under this subpart to assess its compliance with the applicable requirements of this section.

(d) *Agreement.* An agent, broker, or web-broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs must comply with the terms of an agreement between the agent, broker, or web-broker and the Exchange under which the agent, broker, or web-broker at least:

* * * * *

(2) Receives training in the range of QHP options and insurance affordability programs, except that a licensed agent or broker entity that registers with the Federally-facilitated Exchange in its capacity as a business organized under the laws of a State, and not as an individual person, and direct enrollment technology providers are exempt from this requirement; and

* * * * *

(e) *Compliance with State law.* An agent, broker, or web-broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs must comply with applicable State law related to agents, brokers, or web-brokers including applicable State law related to confidentiality and conflicts of interest.

(f) * * *

(1) An agent, broker, or web-broker may terminate its agreement with HHS

by sending to HHS a written notice at least 30 days in advance of the date of intended termination.

(2) The notice must include the intended date of termination, but if it does not specify a date of termination, or the date provided is not acceptable to HHS, HHS may set a different termination date that will be no less than 30 days from the date on the agent's, broker's, or web-broker's notice of termination.

(3) Prior to the date of termination, an agent, broker, or web-broker should—

(i) Notify applicants, qualified individuals, or enrollees that the agent, broker, or web-broker is assisting, of the agent's, broker's, or web-broker's intended date of termination;

* * * * *

(4) When the agreement between the agent, broker, or web-broker and the Exchange under paragraph (d) of this section is terminated under paragraph (f) of this section, the agent, broker, or web-broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's, broker's, or web-broker's agreement with the Exchange under § 155.260(b) will also be terminated through the termination without cause process set forth in that agreement. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(g) * * *

(1) If, in HHS's determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe, HHS may terminate an agent's, broker's, or web-broker's agreement with the Federally-facilitated Exchange for cause.

(2) An agent, broker, or web-broker may be determined noncompliant if HHS finds that the agent, broker, or web-broker violated—

* * * * *

(iii) Any State law applicable to agents, brokers, or web-brokers, as required under paragraph (e) of this section, including but not limited to State laws related to confidentiality and conflicts of interest; or

(iv) Any Federal law applicable to agents, brokers, or web-brokers.

* * * * *

(3)(i) Except as provided in paragraph (g)(3)(ii) of this section, HHS will notify the agent, broker, or web-broker of the specific finding of noncompliance or pattern of noncompliance made under paragraph (g)(1) of this section, and after 30 days from the date of the notice, may terminate the agreement for cause if the matter is not resolved to the satisfaction of HHS.

(ii) HHS may immediately terminate the agreement for cause upon notice to the agent or broker without any further opportunity to resolve the matter if an agent or broker fails to maintain the appropriate license under State law as an agent, broker, or insurance producer in every State in which the agent or broker actively assists consumers with applying for advance payments of the premium tax credit or cost-sharing reductions or with enrolling in QHPs through the Federally-facilitated Exchanges.

(4) After the applicable period in paragraph (g)(3) of this section has elapsed and the agreement under paragraph (d) of this section is terminated, the agent, broker, or web-broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of a qualified individual, qualified employer, or qualified employee in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's, broker's, or web-broker's agreement with the Exchange under § 155.260(b)(2) will also be terminated through the process set forth in that agreement. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(5) * * *

(i)(A) If HHS reasonably suspects that an agent, broker, or web-broker may have engaged in fraud, or in abusive conduct that may cause imminent or ongoing consumer harm using personally identifiable information of an Exchange enrollee or applicant or in connection with an Exchange enrollment or application, HHS may temporarily suspend the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under

§ 155.260(b) for up to 90 calendar days. Suspension will be effective on the date of the notice that HHS sends to the agent, broker, or web-broker advising of the suspension of the agreements.

(B) The agent, broker, or web-broker may submit evidence in a form and manner to be specified by HHS, to rebut the allegation during this 90-day period. If the agent, broker, or web-broker submits such evidence during the suspension period, HHS will review the evidence and make a determination whether to lift the suspension within 30 days of receipt of such evidence. If the rebuttal evidence does not persuade HHS to lift the suspension, or if the agent, broker, or web-broker fails to submit rebuttal evidence during the suspension period, HHS may terminate the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause under paragraph (g)(5)(ii) of this section.

(ii) If there is a finding or determination by a Federal or State entity that an agent, broker, or web-broker engaged in fraud, or abusive conduct that may result in imminent or ongoing consumer harm, using personally identifiable information of Exchange enrollees or applicants or in connection with an Exchange enrollment or application, HHS will terminate the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for cause. The termination will be effective starting on the date of the notice that HHS sends to the agent, broker, or web-broker advising of the termination of the agreements.

(iii) During the suspension period under paragraph (g)(5)(i) of this section and following termination of the agreements under paragraph (g)(5)(i)(B) or (g)(5)(ii) of this section, the agent, broker, or web-broker will not be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

* * * * *

(h) *Request for reconsideration of termination for cause from the Federally-facilitated Exchange*—(1) *Request for reconsideration.* An agent, broker, or web-broker whose agreement with the Federally-facilitated Exchange has been terminated may request reconsideration of such action in the manner and form established by HHS.

(2) *Timeframe for request.* The agent, broker, or web-broker must submit a request for reconsideration to the HHS reconsideration entity within 30 calendar days of the date of the written notice from HHS.

(3) *Notice of reconsideration decision.* The HHS reconsideration entity will provide the agent, broker, or web-broker with a written notice of the reconsideration decision within 30 calendar days of the date it receives the request for reconsideration. This decision will constitute HHS's final determination.

* * * * *

(i) *Use of agents' and brokers' and web-brokers' internet websites for SHOP.* For plan years beginning on or after January 1, 2015, in States that permit this activity under State law, a SHOP may permit agents, brokers, and web-brokers to use an internet website to assist qualified employers and facilitate enrollment of enrollees in a QHP through the Exchange, under paragraph (c)(3) of this section.

(j) * * *

(1) An agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs sold through a Federally-facilitated Exchange, must—

* * * * *

(3) If an agent, broker, or web-broker fails to provide correct information, he, she, or it will nonetheless be deemed in compliance with paragraphs (j)(2)(i) and (ii) of this section if HHS determines that there was a reasonable cause for the failure to provide correct information and that the agent, broker, or web-broker acted in good faith.

(k) * * *

(1) If HHS determines that an agent, broker, or web-broker has failed to comply with the requirements of this section, in addition to any other available remedies, that agent, broker, or web-broker—

* * * * *

(2) HHS will notify the agent, broker, or web-broker of the proposed imposition of penalties under paragraph (k)(1)(i) of this section as part of the termination notice issued under paragraph (g) and, after 30 calendar days from the date of the notice, may impose the penalty if the agent, broker, or web-broker has not requested a reconsideration under paragraph (h) of this section. The proposed imposition of penalties under paragraph (k)(1)(ii) of this section will follow the process outlined under § 155.285.

(3) HHS may immediately suspend the agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction.

(l) *Application to State Exchanges using a Federal platform.* An agent, broker, or web-broker who enrolls qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through an State Exchange using a Federal platform, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through an State Exchange using a Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.

(m) *Web-broker agreement suspension, termination, and denial and information collection.* (1) A web-broker's agreement executed under paragraph (d) of this section, may be suspended or terminated under paragraph (g) of this section, and a web-broker may be denied the right to enter into agreements with the Federally-facilitated Exchanges under paragraph (k)(1)(i) of this section, based on the actions of its officers, employees, contractors, or agents, whether or not the officer, employee, contractor, or agent is registered with the Exchange as an agent or broker.

(2) A web-broker's agreement executed under paragraph (d) of this section may be suspended or terminated under paragraph (g) of this section, and a web-broker may be denied the right to enter into agreements with the Federally-facilitated Exchanges under paragraph (k)(1)(i) of this section, if it is under the common ownership or control or is an affiliated business of another web-broker that had its agreement suspended or terminated under paragraph (g) of this section.

(3) The Exchange may collect information from a web-broker during its registration with the Exchange under paragraph (d)(1) of this section, or at another time on an annual basis, in a form and manner to be specified by HHS, sufficient to establish the identities of the individuals who comprise its corporate ownership and leadership and to ascertain any corporate or business relationships it has with other entities that may seek to register with the Federally-facilitated Exchange as web-brokers.

- 16. Section 155.221 is amended by:
- a. Revising the section heading;
- b. Redesignating paragraphs (a), (b), and (c) as paragraphs (e), (f), and (g), respectively;
- c. Adding new paragraphs (a), (b), and (c) and adding paragraph (d);
- d. Revising newly redesignated paragraphs (e), (f) introductory text, (f)(2) through (4) and (6) and (7), and (g); and
- e. Adding paragraph (h).

The revisions and additions read as follows:

§ 155.221 Standards for direct enrollment entities and for third-parties to perform audits of direct enrollment entities.

(a) *Direct enrollment entities.* The Federally-facilitated Exchanges will permit the following entities to assist consumers with direct enrollment in QHPs offered through the Exchange in a manner that is considered to be through the Exchange, to the extent permitted by applicable State law:

- (1) QHP issuers that meet the applicable requirements in this section and § 156.1230 of this subchapter; and
- (2) Web-brokers that meet the applicable requirements in this section and § 155.220.

(b) *Direct enrollment entity requirements.* For the Federally-facilitated Exchanges, a direct enrollment entity must:

- (1) Display and market QHPs and non-QHPs on separate website pages on its non-Exchange website;
- (2) Prominently display a standardized disclaimer in the form and manner provided by HHS;
- (3) Limit marketing of non-QHPs during the Exchange eligibility application and QHP plan selection process in a manner that minimizes the likelihood that consumers will be confused as to what products are available through the Exchange and what products are not;
- (4) Demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's internet website being used to complete an Exchange

eligibility application or a QHP selection; and

(5) Comply with applicable Federal and State requirements.

(c) *Direct enrollment entity application assister requirements.* For the Federally-facilitated Exchanges, to the extent permitted under state law, a direct enrollment entity may permit its direct enrollment entity application assisters, as defined at § 155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, provided that such direct enrollment entity ensures that each of its direct enrollment entity application assisters meets the requirements in § 155.415(b).

(d) *Federally-facilitated Exchange direct enrollment entity suspension.* HHS may immediately suspend the direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS's satisfaction.

(e) *Third parties to perform audits of direct enrollment entities.* A direct enrollment entity must engage an independent, third-party entity to conduct an initial and annual review to demonstrate the direct enrollment entity's operational readiness and compliance with applicable direct enrollment entity requirements in accordance with paragraph (b)(4) of this section prior to the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection. The third-party entity will be a downstream or delegated entity of the direct enrollment entity that participates or wishes to participate in direct enrollment.

(f) *Third-party auditor standards.* A direct enrollment entity must satisfy the requirement to demonstrate operational readiness under paragraph (e) of this section by engaging a third-party entity that executes a written agreement with the direct enrollment entity under which the third-party entity agrees to comply with each of the following standards:

* * * * *

(2) Adheres to HHS specifications for content, format, privacy, and security in the conduct of an operational readiness review, which includes ensuring that direct enrollment entities are in

compliance with the applicable privacy and security standards and other applicable requirements;

(3) Collects, stores, and shares with HHS all data related to the third-party entity's audit of direct enrollment entities in a manner, format, and frequency specified by HHS until 10 years from the date of creation, and complies with the privacy and security standards HHS adopts for direct enrollment entities as required in accordance with § 155.260;

(4) Discloses to HHS any financial relationships between the entity and individuals who own or are employed by a direct enrollment entity for which it is conducting an operational readiness review;

* * * * *

(6) Ensures, on an annual basis, that appropriate staff successfully complete operational readiness review training as established by HHS prior to conducting audits under paragraph (e) of this section;

(7) Permits access by the Secretary and the Office of the Inspector General or their designees in connection with their right to evaluate through audit, inspection, or other means, to the third-party entity's books, contracts, computers, or other electronic systems, relating to the third-party entity's audits of a direct enrollment entity's obligations in accordance with standards under paragraph (e) of this section until 10 years from the date of creation of a specific audit; and

* * * * *

(g) *Multiple auditors.* A direct enrollment entity may engage multiple third-party entities to conduct the audit under paragraph (e) of this section.

(h) *Application to State Exchanges using a Federal platform.* A direct enrollment entity that enrolls qualified individuals in coverage in a manner that constitutes enrollment through a State Exchange using a Federal platform, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through a State Exchange using a Federal platform must comply with all applicable federally-facilitated Exchange standards in this section.

■ 17. Section 155.415 is revised to read as follows:

§ 155.415 Allowing issuer or direct enrollment entity application assisters to assist with eligibility applications.

(a) *Exchange option.* An Exchange, to the extent permitted by State law, may permit issuer application assisters and direct enrollment entity application assisters, as defined at § 155.20, to assist

individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and insurance affordability programs, provided that such issuer application assisters or direct enrollment entity application assisters meet the requirements set forth in paragraph (b) of this section.

(b) *Application assister requirements.* If permitted by an Exchange under paragraph (a) of this section, and to the extent permitted by State law, an issuer may permit its issuer application assisters and a direct enrollment entity may permit its direct enrollment entity application assisters to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, provided that such issuer or direct enrollment entity ensures that each of its issuer application assisters or direct enrollment entity application assisters at least—

(1) Receives training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations, and for application assisters providing assistance in the Federally-facilitated Exchanges or a State Exchange using a Federal platform, the assisters must fulfill this requirement by completing registration and training in a form and manner to be specified by HHS;

(2) Complies with the Exchange's privacy and security standards adopted consistent with § 155.260; and

(3) Complies with applicable State law related to the sale, solicitation, and negotiation of health insurance products, including any State licensure laws applicable to the functions to be performed by the issuer application assister or direct enrollment entity application assister; confidentiality; and conflicts of interest.

■ 18. Section 155.420 is amended—

■ a. By revising paragraphs (a)(5) and (b)(2)(iv);

■ b. In paragraph (d)(6)(ii) by removing “; or” and adding in its place “;”;

■ c. In paragraph (d)(6)(iii) by removing “.” and adding in its place “;”;

■ d. In paragraph (d)(6)(iv) by removing “;” and adding in its place “; or”; and

■ e. By adding paragraph (d)(6)(v).

The revisions and addition reads as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(5) *Prior coverage requirement.*

Qualified individuals who are required to demonstrate coverage in the 60 days

prior to a qualifying event can either demonstrate that they had minimum essential coverage as described in 26 CFR 1.5000A-1(b) or demonstrate that they had coverage as described in paragraphs (d)(1)(iii) through (iv) of this section for 1 or more days during the 60 days preceding the date of the qualifying event; lived in a foreign country or in a United States territory for 1 or more days during the 60 days preceding the date of the qualifying event; are an Indian as defined by section 4 of the Indian Health Care Improvement Act; or lived for 1 or more days during the 60 days preceding the qualifying event or during their most recent preceding enrollment period, as specified in §§ 155.410 and 155.420, in a service area where no qualified health plan was available through the Exchange.

(b) * * *
(2) * * *

(iv) If a qualified individual, enrollee, or dependent, as applicable, loses coverage as described in paragraph (d)(1) or (d)(6)(iii) of this section, gains access to a new QHP as described in paragraph (d)(7) of this section, becomes newly eligible for enrollment in a QHP through the Exchange in accordance with § 155.305(a)(2) as described in paragraph (d)(3) of this section, or becomes newly eligible for advance payments of the premium tax credit in conjunction with a permanent move as described in paragraph (d)(6)(iv) of this section, and if the plan selection is made on or before the day of the triggering event, the Exchange must ensure that the coverage effective date is the first day of the month following the date of the triggering event. If the plan selection is made after the date of the triggering event, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the following month, at the option of the Exchange.

* * * * *
(d) * * *
(6) * * *

(v) At the option of the Exchange, the qualified individual, or his or her dependent—

- (A) Experiences a decrease in household income;
(B) Is newly determined eligible by the Exchange for advanced payments of the premium tax credit; and
(C) Had minimum essential coverage as described in 26 CFR 1.5000A-1(b) for one or more days during the 60 days preceding the date of the financial change.

* * * * *

■ 19. Section 155.605 is amended by adding paragraph (e)(5) to read as follows:

§ 155.605 Eligibility standards for exemptions.

* * * * *
(e) * * *

(5) General Hardship. The IRS may allow an applicant to claim the exemption specified in HHS Guidance published September 12, 2018, entitled, "Guidance on Claiming a Hardship Exemption through the Internal Revenue Service (IRS)" (see https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf) and in IRS Notice 2019-05 (see https://www.irs.gov/pub/irs-drop/n-19-05.pdf), for the 2018 tax year.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 20. The authority citation for part 156 continues 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.

■ 21. Section 156.122 is amended by adding paragraph (d)(3) to read as follows:

§ 156.122 Prescription drug benefits.

* * * * *
(d) * * *

(3) For plan years beginning on or after January 1, 2020, QHP issuers in a Federally-facilitated Exchange must notify HHS annually in an HHS-specified format of any mid-year formulary changes made in the prior plan year consistent with 45 CFR 147.106(e).

* * * * *

■ 22. Section 156.130 is amended by adding paragraph (h) to read as follows:

§ 156.130 Cost-sharing requirements.

* * * * *

(h) Use of generic drugs and coupons. For plan years beginning on or after January 1, 2020:

(1) Notwithstanding any other provision of this section, for plans that cover both a brand drug that is a prescription drug and its generic equivalent, only the amount of cost sharing that would have been paid for the generic equivalent is required to count toward the annual limitation on cost sharing as defined in paragraph (a) of this section when:

(i) An enrollee purchases a brand drug, if a generic alternative is available and medically appropriate for the enrollee;

(ii) The plan has an exceptions process under section 156.122(c) of this subpart, and coverage of the brand drug has not been required under that process; and

(iii) Notwithstanding the general rule that all prescription drugs covered by such a plan are considered EHB, the plan treats the covered brand drug as being in addition to EHB under the circumstances described in this paragraphs (h)(1)(i) and (ii) of this section.

(2) Notwithstanding any other provision of this section, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent is not required to be counted toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

■ 23. Section 156.280 is amended by revising the section heading and adding paragraph (c)(3) to read as follows:

§ 156.280 Rules relating to coverage of abortion services and segregation of premiums for such services.

* * * * *

(c) * * *

(3) Subject to paragraphs (a) and (b) of this section, for plan years 2020 and beyond, if a QHP issuer provides coverage of services described in paragraph (d)(1) of this section in one or more QHPs at any actuarial value level of coverage specified at § 156.140 of this part, the QHP issuer must also offer throughout each service area in the Exchange in which it offers such coverage at least one QHP at any metal level that provides otherwise identical benefits to one of the QHPs providing coverage of services described in paragraph (d)(1) of this section, but that omits coverage of such services to the extent permissible under applicable state law.

* * * * *

■ 24. Section 156.1230 is amended by—

- a. Removing and reserving paragraph (a)(2);
b. Revising paragraph (b)(1);
c. Removing paragraph (b)(2); and
d. Redesignating paragraph (b)(3) as (b)(2).

The revisions read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(1) The QHP issuer must comply with applicable requirements in § 155.221 of this subchapter.

* * * * *

Dated: December 14, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

RIN 0648-BI44

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to U.S. Air Force Launches and Operations at Vandenberg Air Force Base, California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS has received a request from the U.S. Air Force (USAF) for authorization to take marine mammals incidental to launching space launch vehicles, intercontinental ballistic and small missiles, and aircraft and helicopter operations at Vandenberg Air Force Base (VAFB) from March 2019 to March 2024. As required by the Marine Mammal Protection Act (MMPA), NMFS is proposing regulations to govern that take, and requests comments on the proposed regulations. NMFS will consider public comments prior to making any final decision on the issuance of the requested incidental take regulations and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than February 22, 2019.

ADDRESSES: You may submit comments, identified by NOAA-NMFS-2018-0047, by any of the following methods:

- **Electronic submissions:** submit all electronic public comments via the Federal eRulemaking Portal, Go to www.regulations.gov/

#!docketDetail;D=NOAA-NMFS-2018-0047, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments. Alternately, electronic comments may be emailed to ITP.laws@noaa.gov.

- **Mail:** Submit comments to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910-3225.

Instructions: 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 by NMFS. 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.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender may 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). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Jordan Carduner, Office of Protected Resources, NMFS; phone: (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Availability

A copy of the USAF’s application and any supporting documents, as well as a list of the references cited in this document, may be obtained online at: www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act. In case of problems accessing these documents, please call the contact listed above (see **FOR FURTHER INFORMATION CONTACT**).

Purpose and Need for Regulatory Action

This proposed rule would establish a framework under the authority of the MMPA (16 U.S.C. 1361 *et seq.*) to allow for the authorization of take of marine mammals incidental to launching space launch vehicles, intercontinental ballistic and small missiles, and aircraft and helicopter operations at VAFB.

We received an application from the USAF requesting the five-year regulations and authorization to take marine mammals. Take would occur by

Level B harassment incidental to launch noise and sonic booms. Please see “Background” below for definitions of harassment.

Legal Authority for the Proposed Action

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region for up to five years if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity and other means of effecting the “least practicable adverse impact” on the affected species or stocks and their habitat (see the discussion below in the “Proposed Mitigation” section), as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I, provide the legal basis for issuing this proposed rule containing five-year regulations, and for any subsequent LOAs. As directed by this legal authority, this proposed rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Proposed Rule

Following is a summary of the major provisions of this proposed rule regarding space launch activities. These measures include:

- Required acoustic monitoring to measure the sound levels associated with the proposed activities.
- Required biological monitoring to record the presence of marine mammals during the proposed activities and to document responses to the proposed activities.
- Mitigation measures to minimize harassment of the most sensitive marine mammal species.

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.