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Affordable Care Act: Proposed HHS Notice of Benefit and Payment Parameters for 2020 (CMS-9926-P)
Summary of Proposed Rule

January 23, 2019

On January 18, 2019, the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) placed on public display its proposed Notice of Benefit and Payment Parameters for 2020 (Payment Notice). The proposed Payment Notice sets out policy changes related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters and cost-sharing reductions; and user fees for federally-facilitated Exchanges (FFEs) and state-based Exchanges (SBEs) on the Federal Platform. It is scheduled to be published in the *Federal Register* on January 24, 2019; **comments are due on February 19, 2019.**

The proposed rule is accompanied by release of a fact sheet.[1] CMS also released the draft Letter to Issuers in the FFEs[2], the draft 2020 Actuarial Value Calculator and Methodology, the 2019 Rate Review Timeline Bulletin, Key Dates for Calendar Year 2019, and Guidance on Unified Rate Review Timeline at https://www.cms.gov/cciio/index.html.

Summary of Major Provisions

Risk Adjustment Program. In addition to regular updates to its risk adjustment model, CMS proposes to make a limited-set data file of enrollee-level data available to the public based on state External Data Gathering Environment (EDGE) submissions. CMS proposes a number of changes to Risk Adjustment Data Validation (RADV) methods, sample sizes, and error rates; and would codify the RADV process for issuers exiting a market, single issuer markets, and negative error rate outlier markets

Web-based Direct Enrollment Providers. CMS proposes to make major revisions to provisions relating to users of non-Exchange direct enrollment web-sites, including the requirements for the information displayed on those websites, and standards for the companies providing the web-based enrollment. Some of the proposed revisions are intended to streamline regulatory requirements; others would increase oversight, program integrity, or improve information technology security.

Navigator & Other Enrollment Assisters. CMS proposes to reduce certain functional and training requirements for Navigators and proposes additional regulatory standards for all enrollment assisters when assisting with enrollment and selection of qualified health plans (QHPs) using a web-broker website.

[1] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Proposed-2020-HHS-Fact-Sheet.PDF.
[2] https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-2020-Letter-to-Issuers-in-the-Federally-facilitated-Exchanges.pdf.

Special Enrollment Period. CMS proposes a new special enrollment period for individuals enrolled in non-Exchange individual market coverage who experience a decrease in income and receive a new determination of eligibility for advance payments of premium tax credit (APTC).

Prescription Drug Benefits. CMS proposes to permit health insurers in the individual and group markets for insurance to make mid-year formulary changes when a new generic medication becomes available. CMS would also permit issuers to exclude certain amounts from annual limitations on cost sharing. Specifically, issuers would be able to exclude some or all of a beneficiary's copayments for a brand drug when the both the brand and the generic are included in the plan's formulary. They would also be permitted to exclude copayments that are made using manufacturer copayment coupons or other forms of direct support offered by manufacturers to insured individuals.

Coverage Options That Exclude Coverage for Abortions. HHS would require QHP issuers that offer plans with coverage for non-Hyde abortion services (abortion services beyond those necessary to save the life of the woman, or in the case of rape or incest) to also offer a "mirror QHP" that would exclude such coverage.

Premium Adjustment Percentage. HHS proposes a change to its methodology for calculating the premium adjustment percentage. Beginning with the 2020 plan year, HHS would incorporate into the premium adjustment percentage, the rate of growth of individual market health insurance. This change would increase the premium adjustment percentage, resulting in higher cost-sharing ceilings for beneficiaries; lower APTCs; lower eligibility for, and enrollment in subsidized Exchange plans; and lower federal spending.

In addition, HHS notes in the preamble that it is alerting stakeholders that it supports a legislative solution that would appropriate cost-sharing reduction (CSR) payments and end the practice of silver loading, and reminds issuers that exclusion of Medication-Assisted-Therapy (MAT) drugs for the treatment of opioid use disorder while covering the same drugs for other medically necessary purposes would be considered a potentially discriminatory benefit design.

Summary of Final 2019 and Proposed 2020 Parameters: Selected Provisions		
Provision	**Final 2019 Plan Year**	**Proposed 2020 Plan Year**
Annual increase in selected parameters based on "premium adjustment percentage"	7.7%	3.6%
Required contribution percentage for exemption from mandate	8.30%	8.39%
Annual enrollee out-of- pocket cost-sharing maximum	$7,900/$15,800*	$8,200/$16,400*
Reduced out-of-pocket cost-sharing maximums at specified percentages of the federal poverty level (FPL) • 200-250% of FPL • 150-200% of FPL	 $6,300/$12,600* $2,600/$5,200* $2,600/$5,200*	 $6,550/$13,100* $2,700/$5,400 $2,700/$5,400

Summary of Final 2019 and Proposed 2020 Parameters: Selected Provisions		
• 100-150% of FPL		
Risk adjustment program annual user fee (per billable enrollee)	$1.80	$2.16
Federally Facilitated Exchange user fee	3.5% of premium	3.0% of premium
State-based Exchange with Federal Platform (SBE-FP) user fee	3.0% of monthly premium	2.5% of monthly premium
* Amount of out-of-pocket limits and deductibles presented as "single policy/family policy."		

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I. Background

A. Legislative and Regulatory Overview

HHS reviews the legislative and regulatory history related to the implementation of the Exchanges and related topics. Regulatory developments preceding the publication of the Proposed Notice of Benefit and Payment Parameters for 2020 are summarized below:

Provision	Proposed Rule (or Guidance)	Final Rule
Premium stabilization		
• Outline of premium stabilization programs	July 15, 2011 (76 *FR* 41930)	March 23, 2012 (77 *FR* 17220)
• Benefit and payment parameters for 2014	December 7, 2012 (77 *FR* 73118)	March 11, 2013 (78 *FR* 15410)
• Benefit and payment parameters for 2015	December 2, 2013 (78 *FR* 72322)	March 11, 2014 (79 *FR* 13744)

Provision	Proposed Rule (or Guidance)	Final Rule
• Benefit and payment parameters for 2016	November 26, 2014 (79 *FR* 70673)	February 27, 2015 (80 *FR* 10749)
• Benefit and payment parameters for 2017	December 2, 2015 (80 *FR* 75487)	March 8, 2016 (81 *FR* 12203)
• Benefit and payment parameters for 2018	September 6, 2016 (81 *FR* 61455)	December 22, 2016 (81 *FR* 94058)
• Market Stabilization		April 18, 2017 (82 FR 18346)
• Benefit and payment parameters for 2019	November 2, 2017 (81 FR 51042)	April 17, 2018 (83 FR 16930)
Program Integrity Related to Exchanges and Premium Stabilization Programs	June 19, 2013 (78 *FR* 37032)	August 30, 2013 (78 *FR* 54070) October 30, 2013 (78 *FR* 65046) November 9, 2018 (83 FR 56015)
Exchanges, Essential Health Benefits and Actuarial value (AV)	November 26, 2012 (77 *FR* 70644) March 21, 2014 (79 *FR* 15808)	February 25, 2013 (78 *FR* 12834) May 27, 2014, (79 *FR* 30240) April 18, 2017, (82 *FR* 18346) [expanded de minimis range for AV levels]
• Premium adjustment percentage standards	February 25, 2013 (78 *FR* 12834)	2015 Payment Notice March 11, 2014 (79 *FR* 13743); Amended in the 2015 Market Standards Rule March 21, 2014 (79 *FR* 15808)
• Standards for administration and payment of cost-sharing reductions for SHOP	March 11, 2013 (78 *FR* 15541) – note this was an interim final rule	October 30, 2013 (78 *FR* 65046)
• Exchange user fee	March 11, 2013 (78 *FR* 15410)	July 2, 2013 (78 *FR* 39870 – Preventive Services Rule)
• State Exchanges - federal standards	August 3, 2010 (75 *FR* 45584) - Request for comment; November 18, 2010 – Initial Guidance to States on Exchanges; July 15, 2011 (76 *FR* 41866) Additional standards; standardized options; requirements for state Exchanges using federal platform; December 2, 2015 (80 *FR* 75847)	March 27, 2012 (78 *FR* 18310) March 8, 2016 (81 *FR* 12203)
• Exchange functions for individual market, eligibility determinations, standards	August 17, 2011 (76 *FR* 51202)	March 27, 2012 (78 *FR* 18310) May 11, 2016 (81 *FR* 29146) December 22, 2016 (81 *FR* 94058)

Provision	Proposed Rule (or Guidance)	Final Rule
for employers, special enrollment periods		April 18, 2017 (82 *FR* 18346) – [SEPs and QHP certification]
Minimum Essential Coverage	February 1, 2013 (78 *FR* 7348) November 26, 2014 (79 *FR* 70674)	July 1, 2013 (78 *FR* 39494) February 27, 2015 (80 *FR* 10750)
Market reform rules and rate review	December 23, 2010 (75 *FR* 81004) November 26, 2012 (77 *FR* 70584) March 21, 2014 (79 *FR* 15808)	May 23, 2011 (76 *FR* 29964) September 6, 2011 (76 *FR* 54969) February 27, 2013 (78 *FR* 13406) March 11, 2013 (78 *FR* 15410) May 27, 2014 (79 *FR* 30240) February 27, 2015 (80 *FR* 10749)
Medical Loss Ratio	April 14, 2010 – Request for Comment (75 *FR* 19297); December 1, 2010 – Interim final rule (75 *FR* 74864)	December 7, 2011 – Final with comment period (76 *FR* 76574) May 16, 2012 (77 *FR* 28790) May 27. 2014 (79 *FR* 30339) February 27, 2015 (80 *FR* 10749) March 8, 2016 (81 *FR* 12203) December 22, 2016 (81 *FR* 94183)
Pre-Existing Condition Insurance Plan Program	July 30, 2010 (75 *FR* 45013) – Interim final rule August 30, 2012 – amendment to interim final rule (77 *FR* 52614)	May 22, 2013 (78 *FR* 30218)
Rate Review	December 23, 2010 (75 FR 81003)	May 23, 2011 (76 *FR* 29963), September 6, 2011 (76 *FR* 54969), February 27, 2013 (78 FR 13405), May 27, 2014 (79 *FR* 30239), February 27, 2015 (80 *FR* 10749), March 8, 2016 (81 *FR* 12203), December 22, 2016 (81 *FR* 94058).
Risk Adjustment		May 11, 2018 (83 FR 21925) July 30, 2018 (83 FR 36456) August 10, 2018 (83 FR 39644) December 10, 2018 (83 FR 63419)
Navigator & Non-Navigator Assistants		July 17, 2013 (78 FR 42823)
Prepared by HPA based on this and previous HHS Notice of Benefit and Payment Parameters.		

B. Stakeholder Input

HHS sought advice from stakeholders on policies related to the operation of Exchanges, including the SHOP and the premium stabilization programs, and considered this input in developing the policies in this rule. It solicited input from states on topics including essential health benefits (EHB), qualified health plan (QHP) certifications, Exchanges and risk adjustment. It also consulted with the National Association of Insurance Commissioners, and held meeting with Tribal leaders, issuers, trade groups, consumer advocates and employers.

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

HHS states that the proposals in this rule are focused on maintaining a stable regulatory environment and improve predictability for issuers and enhance the role of states by providing them additional flexibility. HHS also seeks to reduce unnecessary burdens on stakeholders and improve affordability and notes that a number of its proposed changes are intended to reduce prescription drug expenditures.

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

The proposed changes to Part 146 are conforming amendments which correspond to changes discussed below. Those changes would permit mid-year formulary changes under certain circumstances.

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

Under existing rules guaranteeing the availability of coverage, issuers are prohibited from modifying health insurance coverage mid-year except under limited circumstances where the modification is considered a uniform modification. Otherwise changes to individual and group health insurance plans must be made at coverage renewal. Those rules are in existing §147.106(e).

HHS proposes a new paragraph §147.106(e)(5) permitting issuers to make mid-year formulary changes when a generic equivalent of a prescription drug becomes available. Under the provision, a plan would be permitted to add the new generic and remove the equivalent brand drug from its formulary or move the brand drug to a different cost-sharing tier on the formulary.

For an issuer to take advantage of this mid-year modification, it must notify plan enrollees in writing at least 60 days before making the change and all enrollees must have access to the coverage appeals process under §147.136 and the drug exception request process under §156.122(c).

The notification would be required to identify the name of the brand drug subject to change, disclose whether it is removed or moved to a different tier of the formulary, provide the name of the generic equivalent, specify the date of the change, and remind enrollees of the availability of the appeals and exceptions processes available to them.

HHS estimates in the Collection of Information Requirements portion of the preamble that these notices would be of two types: notice of removing a brand drug from a formulary which HHS estimates to cost a total of $8.5 million among the 520 plans that it estimates will do so; and a notice of a change to the cost-sharing tier for a brand name drug which HHS estimates to cost a total of $8.4 million among the 520 plans.

Conforming changes are proposed to §146.152 and §148.122 (Guaranteed renewability provisions.)

HHS seeks comments on whether the flexibility should be limited to only certain issuers such as individual and small group insurance issuers or if a different advance notice period should be required -- of 90 or 120 days, for example.

C. Part 153 – Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

1. Sequestration

As explained by HHS, both the transitional reinsurance program and permanent risk adjustment program are subject to the FY 2019 sequestration.[3] Although the 2016 benefit year was the final year of the transitional reinsurance program, reinsurance payments will continue to be made by HHS in FY 2019 fiscal year. The reinsurance and risk adjustment programs will each be sequestered at a rate of 6.2 percent for payments made from funds collected during FY 2019. Funds sequestered in FY 2019 from the reinsurance and risk adjustment programs will become available for payment to issuers in FY 2020 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs will continue to be sequestered in future fiscal years; any sequestered funding would become available in the fiscal year following that in which it was sequestered.

2. Provisions and Parameters of the Risk Adjustment Program

Standards for administration of the risk adjustment program created by the Affordable Care Act (ACA) are set out in subparts D and G of 45 CFR Part 153. In brief, the risk adjustment program transfers funds from non-grandfathered plans in the individual and small group markets (in and outside of the Exchanges) with lower-cost enrollees to those with higher-cost enrollees. A state may establish a risk adjustment program (with HHS approval) or have HHS do so on its behalf. Currently, no state is operating its own program. HHS is operating risk adjustment in every state beginning for the 2017 benefit year and did not receive any applications from states to operate risk-adjustment for the 2020 benefit year.

[3] See the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year (FY) 2019,https://www.whitehouse.gov/wp-content/uploads/2018/02/Sequestration_Report_February_2018.pdf

a. HHS Risk Adjustment (§153.320)

The HHS risk adjustment model predicts plan liability for an average enrollee based on age, sex, and diagnoses (risk factors). Separate models are used to predict and account for cost differences for adults, children, and infants. In each of 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. In the adult models, enrollment duration factors are also added beginning for the 2017 benefit year, and prescription drug utilization factors (RXCs) beginning for 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.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (i.e., the plan liability risk score) within a geographic rating area is one of the inputs into the risk adjustment payment transfer formula, which determines the payment or charge that an issuer will receive or be required to pay for that plan. Thus, to account for risk across plans, the HHS risk adjustment model predicts average group costs.

(i) Updates to the Risk Adjustment Model Recalibration (§153.320)

HHS proposes to recalibrate the risk adjustment models for the 2020 benefit year using the methodology finalized for the 2019 benefit year. It also will incorporate two years of benefit year EDGE data in the 2020 benefit year risk adjustment model recalibration. Other specific policy changes are described below.

To recalibrate the 2016, 2017 and 2018 benefit year risk adjustment models, HHS used the three most recent years of Truven MarketScan® data. In the 2018 Payment Notice, HHS finalized the collection of enrollee-level EDGE data and the recalibration of the risk adjustment model for the 2019 benefit year using 2016 benefit year EDGE data. It continues its transition to the use of EDGE data and expects that by the 2021 recalibration, it will solely use enrollee-level EDGE data. It believes that this approach will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from earlier benefit years due to differences in the underlying populations in the different data sets.

For the 2020 benefit year, HHS proposes to again blend data from the 2 most recent years of EDGE enrollee-level data (2016 and 2017) and the most recent MarketScan® data (2017) using the methodology described in the 2019 Payment Notice final rule. Because HHS did not have enough time to develop the 2017 MarketScan® dataset for the proposed rule, the 2016 MarketScan® data were used to estimate the coefficients in this proposed rule. HHS states that if it is unable to publish the final risk adjustment model coefficients for the 2020 benefit year in the final rule, it would publish those final coefficients for the 2020 year in later guidance. HHS, however, notes that it believes the draft coefficients provided in this proposed rule are a relatively close approximation to the coefficients that will be the final result of blending the 2016 and 2017 EDGE data with the 2017 MarketScan® data.

HHS does not propose changes to age-sex, Hierarchical Condition Categories (HCCS), or enrollment duration categories. HHS does, however, proposes a change to one RXC category for the 2020 benefit year adult model. For 2020, HHS proposes to make a pricing adjustment to the Hepatitis C RXC to mitigate overprescribing incentives in the adult models. It proposes to constrain the Hepatitis C coefficient to the average expected costs of Hepatitis C drugs. As a result, the Hepatitis C RXC and the RXC-HCC interaction coefficients would be affected. **HHS requests comment on ways to better anticipate and adjust drug categories in the HHS risk adjustment adult models to account for rapidly changing drug prices, and in the plan liability expenditures calculation to take into account rebates, discounts, and other price concessions that are passed through to plans.**

(ii) High-cost Risk Pooling (§155.320)

HHS proposes to retain the same high-cost risk pool adjustment that applied in 2018 and 2019 and to maintain cost-sharing reduction factors finalized in the 2017 Payment Notice. With respect to the high-cost risk pool adjustment, HHS excludes a percentage of costs above a certain threshold in calculating plan liability risk scores and insurers receive a percentage of costs above the threshold. The threshold is proposed to be set at $1 million with a 60% coinsurance rate consistent with prior years.

(iii) Cost-sharing Reduction Adjustments

Also consistent with prior years, cost sharing reductions are incorporated into the risk adjustment models to account for increased plan liability due to higher utilization of health care services by individuals receiving cost-sharing reductions. Those amounts are displayed in Table 7 of the public display version of the proposed rule. For Massachusetts, HHS will continue to use a cost-sharing reduction factor of 1.12 for all Massachusetts wrap-around plans.

The draft risk adjustment model coefficients for the 2020 benefit year risk adjustment program are listed in Tables 1, 3, and 4 of this proposed rule (see pages 44-62 in the public display copy).

(iv) Model Performance Statistics (§153.320)

HHS reports the R-Squared statistic, which calculates the percentage of individual variation explained by a measure, to show the predictive accuracy of the risk adjustment models overall. For each of the HHS models, the R-Squared (as well as the predictive ratio) are in the range of published estimates for concurrent risk adjustment models. Because HHS blends these coefficients from separately solved models based on MarketScan® and enrollee-level EDGE data, HHS publishes the R-squared statistic for each model and benefit year separately (see Table 8 in the proposed rule).

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

HHS reviews its methodology for transferring risk adjustment payments. The formula determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment. The total payment or charge is calculated to balance the state market risk pool with the goal of encouraging issuers to compete on the basis of price and quality of their plans and not risk selection.

HHS also provides its justification for operating the risk adjustment program in a budget-neutral manner. As part of a budget neutral approach, it uses the statewide average premium as the cost-scaling factor in the transfer formula. It notes that using the statewide average premium instead of each plan's own premium has raised concerns among some stakeholders that it penalizes issuers with efficient care management. HHS acknowledges the concern but points out that having more efficient care management does not result in enrolling lower-than-average risk enrollees, so these plans should not be disadvantaged in the risk adjustment transfer. In addition, using plans' premiums may be subject to greater volatility than a statewide average—so its use could introduce greater pricing instability.

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

HHS proposes to continue its policy from 2018 and 2019 to add to the risk adjustment methodology additional transfers to reflect the payments and charges assessed with respect to the cost of high-risk enrollees. This results in the addition of one term to reflect 60% of costs above $1 million and another term to reflect a percentage of the per member per month (PMPM) premium adjustment to the transfer formula for the high-cost enrollee pool. This step maintains the balance of payment and charges within the risk adjustment program. HHS proposes to maintain this same adjustment to the risk adjustment transfers for the 2020 benefit year.

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

In the 2019 Payment Notice, HHS provided states, starting with the 2020 benefit year, with the flexibility to request a reduction to the otherwise applicable risk adjustment transfers calculated under the HHS-operated methodology. This exceptions request recognizes that for some states that deviate significantly from the national dataset used by HHS for this purpose, a further adjustment to the statewide average premium may better account for differences between the plan premium estimate reflecting adverse selection and the plan premium estimate not reflecting selection in their state market risk pools. Allowing certain state-by-state adjustments to the HHS risk adjustment program can account for state-specific differences in risk without the necessity for states to undertake operation of their own risk adjustment program.

Under the policy, states have the flexibility to request a reduction to the otherwise applicable risk adjustment transfers in the individual, small group or merged market by up to 50 percent.

In this proposed rule, HHS would amend §153.320(d)(2) to require that such requests must be submitted along with supporting documentation by August 1st of the calendar year that is 2 calendar years prior to the beginning of the benefit year.

In addition, HHS would amend §153.320(d)(3) to add language to provide that if the state requests that HHS not make certain supporting evidence and analysis publicly available because it contains trade secrets or confidential information, HHS will honor such requests. Instead it would make only the supporting evidence submitted by the state that is not a trade secret or confidential information available on its website. Under the proposal, HHS would release only information that is not a trade secret or confidential as defined under the HHS FOIA regulations.[4] States making this request would need to provide a version of their documentation for public release that redacts any information it doesn't want made public as well as an unredacted version for HHS.

HHS notes that it has received a request from Alabama to reduce risk adjustment transfers by 50% for the 2020 benefit year for its small group market. The request states that the presence of a dominant carrier has prevented the HHS methodology from working as well as it does in other markets that have a more balanced distribution of market share. The state indicates that such an adjustment would result in increases to premiums that would not exceed 1 percent. HHS seeks comment on this request.[5]

(iii) The Payment Transfer Formula

HHS does not propose changes to the payment transfer formula for 2020. The formula is described in the 2014 Payment Notice (78 FR 15430 through 15434) and is republished in this proposed Payment Notice's preamble. (See pages 72-75 of the public display copy.)

HHS notes that it continues to remove a portion of administrative costs (14%) from the statewide average premium that do not vary with claims.

c. Risk adjustment issuer data requirements (§153.610 and §153.710)

HHS notes that in the 2018 Payment Notice, it stated that it would consider using enrollee-level EDGE data to produce a public use file for government entities and independent researchers. To do so, certain data elements would need to be eliminated including dates to comply with the safe harbor for de-identification of data at 45 CFR 164.514. Instead, HHS proposes to make a limited data set available that would include dates. If finalized, enrollee-level EDGE data would become available on an annual basis starting with the 2016 benefit year. It would not include direct identifiers of individuals or relatives, employers, or household members. The data set would be available to requesters using the data for research, public health, or health care operations purposes and a data use agreement would need to be signed.

In comments offered in response to the 2018 Payment Notice, a number of data elements were identified as being useful to researchers including enrollees' geographic identifiers, enrollees'

[4] See 45 CFR §154.215(h)(2).

[5] Documentation submitted by Alabama can be found at the bottom of https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html under the header "Risk Adjustment State Flexibility Requests."

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). HHS notes that if the proposal to make a limited data set is finalized, it will include a claims identifier but other requested data elements are either not available on the EDGE submissions or cannot be extracted due to privacy concerns.

HHS is seeking comment on whether to extract geographic details such as enrollees' state and rating area information and whether such extractions should be provided as part of the public data set made available to researchers or only for use within HHS. It seeks information on a number of other related questions:

- **How geographic details and other data elements could be used to improve risk adjustment, the AV Calculator and methodology, and other HHS programs;**
- **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;**
- **The 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 collection of other data elements listed above that issuers do not currently submit to their EDGE servers, or other data elements not listed above 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, or other research, public health or health care operations.**

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

HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. Under §153.610(f)(2), an issuer of a risk adjustment covered plan, as defined in §153.20, must remit a user fee to HHS equal to the product of its monthly enrollment in the plan and the per enrollee per month risk adjustment user fee specified in the annual HHS Payment Notice for the applicable benefit year. In 2020, HHS will be operating a risk adjustment program in every state.

For the 2020 benefit year, HHS proposes to use the same methodology to estimate administrative expenses to operate the program. HHS estimates the cost for HHS to operate the risk adjustment program on behalf of states for the 2020 benefit year to be approximately $50 million and is finalizing a risk adjustment user fee of $2.16 per billable member per year, or $0.18 PMPM. In the 2019 Payment Notice, HHS finalized the risk adjustment user fee rate at $1.80 per billable enrollee per year or $0.15 PMPM for 2019.

Regulatory Impact Analysis. Table 15 (duplicated below) summarizes the effects of the risk adjustment program on the federal budget from fiscal years 2019 through 2023. HHS does not expect the provisions of this final rule to significantly alter the Congressional Budget Office's estimates of the budget impact of the premium stabilization programs. HHS notes that the transitional risk-corridor and reinsurance provisions of the ACA's premium stabilization

programs have ended. Therefore, the costs associated with those programs are not included in the impact tables.

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.

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

Based on its first two pilot years of risk adjustment data validation (RADV), HHS proposes amendments and clarifications to the RADV program. As background, HHS conducts RADV in any state where HHS is operating risk adjustment on a state's behalf. The validation consists of an initial validation audit and a second validation audit. Each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. 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.

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

Under existing data validation sampling, the current enrollee sample size selected for the risk adjustment initial validation audit is 200 enrollees for each issuer. Beginning with the 2019 benefit year of RADV, HHS proposes to vary the initial validation audit sample size. It proposes two alternative approaches:

(i) Varying sample size based on failure rates, sample precision, and issuer size

One proposed approach would vary sample size based on issuer characteristics, such as issuer size, HCC failure rates, and sample precision. Under this approach HHS would use the 2017 benefit RADV results to incorporate HCC failure rates for the 2019 initial validations. HHS would require a minimum sample size of 400 enrollees for each larger insurer with lower- or higher-than average failure rates and sample sizes that increase based on issuers with poor precision. For issuers with average HCC failure rates, the initial validation audit sample size would remain at 200 enrollees.

The increased sample sizes would apply to issuers who are more than 1.644 standard deviations away from the mean (but who are not outliers, that is above 1.96 standard

deviations) for any HCC failure rate group. The larger sample size could identify more issuers who are outliers.

For very small issuers (below 3,000 enrollees statewide) the sample size would remain at 200. For smaller issuers (between 3,000 and 49,999 enrollees statewide), the sample size would begin at 200 and increase based on the issuer's precision. For larger issuers (50,000 enrollees or more), sample sizes would begin at 400 enrollees and would increase based on the issuer's precision. HHS expects about 55 issuers would be required to provide larger samples out of approximately 500; 40 larger issuers would have their samples increased to a minimum of 400 enrollees; 5 of those 40 would have sample sizes increased to above 400 enrollees; and about 15 smaller issuers will face moderate increases in sample size. The others would remain at about 200.

HHS provides its proposed formulas for determining the precision of a sample of failure rates and estimates sample sizes for issuers of different sizes based on precision rates that vary from below 10% to above 20% for smaller and larger issuers. (See page 95 of the public display copy.)

HHS believes that any increased burden of larger sample sizes for issuers would be outweighed by the increased precision of the RADV results which are used to adjust risk scores and associated risk adjustment transfers.

HHS seeks comment on the year to use for calculating an issuer's enrollment for the applicable RADV benefit year; whether it should use failure rates to determine sample size; and whether HHS should use failure rates for the latest benefit year or multiple prior years when determining an issuer's RADV sample size. In addition, HHS requests comments on any alternative approaches for determining sample sizes for issuers based on, size, HCC failure rates and sample precision that would not be overly burdensome but would increase precision. HHS asks whether larger issuers (over 50,000 enrollees statewide for benefit year being validated) should have larger initial sample sizes, as well as alternative approaches that would provide HHS with data to further refine RADV error rate assumptions while also limiting unnecessary burdens.

(ii) Varying sample size based only on issuer size

HHS is considering an alternative approach for initial RADV audits that would increase sample sizes based on issuer size alone. HHS would use the following four groups:

Issuer Size	Approximate Sample Size for 2019 Benefit Year
Issuers with 51 – 3,000 enrollees	90
Issuers with 3,001 – 20,000 enrollees	250
Issuers with 20,000 – 100,000	400
Issuers with 100,001 and above	500

HHS does not believe, however that this simpler approach would be best; it would increase burden without meaningfully improving precision for issuers with large variances in HCC

failure rates or error rates. In addition, it would impact issuers with good precision as well as those without.

HHS requests comment on whether, if this approach is finalized, further subdivisions of issuers would improve the audits and what those characteristics for the subdivisions should be.

HHS further requests comment on whether it should permit issuers of any size and HCC failure rate to request a larger sample size before the applicable benefit year's initial validation audit begins; whether HHS should use the 2017 benefit year HCC failure rates to develop sample sizes for the 2019 benefit year; and whether further evaluation is necessary before modifying sampling approaches for the initial RADV audit.

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

HHS proposes, beginning with the 2018 benefit year RADV, to shorten the timeframe for issuers to confirm the findings of a second validation audit or risk score error rate, or file a discrepancy report. Under current rules, issuers have 30 days. HHS would shorten that period to within 15 days of the notification by HHS. In addition, HHS clarifies that there are two discrepancy reporting windows under §153.630(d)(2). The first is at the conclusion of the second validation audit in the event there is insufficient agreement between the initial validation audit and the second. The first 15-day calendar window to confirm these findings or file a discrepancy would begin when those reports are issued. The second would begin at the conclusion of the risk score error rate calculation process once HHS has distributed the risk score error rate calculation results to all issuers for the benefit year. The second 15 -day calendar window to confirm the error rates calculations or file a discrepancy would being then.

HHS does not believe this shortened timeframe would be overly burdensome for issuers and asserts that the benefits of more timely resolution of issues would outweigh the disadvantages.

c. Default Data Validation Charge

HHS proposes changes to better distinguish between the default data validation charge assessed under §153.630(b)(10) and the default risk adjustment charge assessed under §153.740(b) among other changes.

The default data validation charge under §153.630(b)(10) is assessed when a covered plan fails to engage an initial validation auditor or submit initial validation audit results. HHS proposes several changes to this provision:

- To replace the phrase "default risk adjustment charge" with "default data validation charge."
- To change the calculation of this charge to be based on enrollment for the benefit year being audited in RADV rather than the benefit year during which transfers would be adjusted as a result of RADV.
- To amend the allocation approach for distributing default data validation charges among issuers. HHS proposes to allocate the charges to RADV compliant issuers (excluding non-

compliant issuers) and issuers exempt from RADV requirements that were part of the same risk pool for that benefit year. (HHS notes that it will publish default data validation charge information in the benefit year's summary report on risk adjustment required under §153.310(e).)

- To clarify that a default data validation charge is separate from risk adjustment transfers for a given benefit year, in contrast to a default risk adjustment charge under §153.740(b) which replaces an issuer's transfer amount for a benefit year. HHS notes that this means that an issuer could owe both a default risk adjustment charge (for the 2018 benefit year) and a default data validation charge (for the 2017 benefit year) in the same calendar year.

d. Second Validation Audit Pairwise Means Test

HHS proposes a change to the statistical subsampling methodology used to compare results between the initial and second validation audits. Under the existing methodology, if a statistical difference is found between the two audits, the second validation auditor tests again using a larger (100 enrollee subsample) to compare the results. Beginning with the 2017 benefit year RADV, when the larger subsample indicates a statistically significant difference, further sampling by the second validation auditor is proposed. At that point, under the proposal, the second validation auditor would test the full initial sample of enrollees. HHS will then determine if the audit results for the second sample should replace those of the first sample using precision analysis.

HHS notes that if any of the proposals to change the initial validation audit sample size are finalized, HHS would maintain a sample size of 200 for these comparisons.

e. Error Estimation for Prescription Drugs

As HHS has incorporated RXCs into risk adjustment models for adults beginning with the 2018 payment year, HHS proposes to incorporate RXC failure rates into the RADV process. Under the existing methodology, only failure rates for HCC groups are used for data validation. HHS is considering several alternative approaches for incorporating RXC failure rates into the RADV audits:

- Add each RXC as a separate factor similar to each HCC and classify the RXCs into groups of low, medium, and high error rates as is currently done for HCCs. Under this approach, the 12 RXCs would be added to the 128 HCCs and there would be 140 total factors for grouping. HHS would then create three groups and assign each HCC and RXC failure rates to one of the three groups reflecting high, medium, and low error rates for all 140 factors. HHS indicates that this would be the simplest approach.
- All RXCs would together be treated as a single HCC grouping. As a result, there would be four groups: High, medium, and low failure HCCs and the RXC group. HHS indicates that this approach would increase the possibility for issuers to be identified as outliers, and the confidence interval for the RXC error rates could be large.

HHS also proposes three approaches to incorporating RXCs into the error rate calculation under the error estimation methodology. These approaches are needed to take into account any RXC-HCC interaction factors in the error rate calculation.

- HHS could add RXCs to the current methodology for calculating error rates without accounting for any HCC-RXC interaction factors. HHS indicates that this would be the simplest approach, but it could oversimplify by not accounting for interactions between the two factors.
- Alternatively, HHS solicits 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 approach, if there is no coefficient, the single component HCC and RXC would not be adjusted by an interaction term. HHS indicates that this approach could provide a more accurate calculation but would add an additional step to the error rate calculation and could result in an over-adjustment for interaction terms.
- Under the third alternative, HHS could 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 RXC would not be adjusted by an interaction term. 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. 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. This proposed approach would have the benefit, however, 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.

HHS solicits comment on whether or not it should adjust for RXC-HCC interactions; how to weight risk score coefficients and account for interaction terms; whether there are alternate approaches that HHS did not describe; or whether it should impose one of the proposed approaches while continuing to evaluate the best approach.

HHS is also considering other ways to incorporate RXCs into the RADV process. One approach could be to treat RXC errors as a data submission issue similar to errors with demographic or enrollment errors in EDGE submissions. In doing so, these errors would be a basis for an adjustment to the applicable benefit year risk score and original transfer amount rather than for the subsequent benefit year risk score.

f. RADV Adjustments in Exiting and Single Issuer Markets and Negative Error Rate Outlier Markets

Under current policy, HHS applies the error rate calculated through the RADV process for the applicable benefit year to plan risk scores in the subsequent benefit year, and then makes risk adjustment payment transfers based on adjusted plan average risk scores in that subsequent benefit year. When an issuer of a risk adjustment covered plan exits a state market following the benefit year being audited, it does not have risk scores or payment transfers in the subsequent benefit year to which HHS can make adjustments. In prior rules, HHS provided an exception to the general rule so that it adjusts the exiting issuer's prior year risk scores and associated transfers where it has been identified as an outlier in RADV.

HHS proposes to amend this policy to provide that if an existing issuer is found to be a negative outlier, HHS will not make adjustments to that issuer's risk score and associated transfers as a result of the negative error rate outlier finding. Under the proposed rule, HHS would only re-open the issuer's risk score and associated risk adjustment transfers in a prior benefit year if the exiting issuer was found to have had a positive error rate and was therefore overpaid or undercharged. This approach is intended to ensure that issuers are made whole when another issuer with a positive error rate exits the state. It would reduce the burden on issuers who would otherwise have their transfers adjusted for a prior benefit year because an issuer with a negative error rate exits the market.

Under the proposal, an exiting issuer would have to exit all markets and risk pools in the state. Small group market issuers with plan years that cross calendar years who exit the market and who only have carry-over coverage ending in the next benefit year would be considered an exiting issuer. The proposal would be effective for the 2017 benefit year RADV and beyond.

HHS also proposes clarifications to how RADV results are applied where an issuer is entering what was previously a sole issuer risk pool (so no risk adjustment transfers were made or calculated.) If the formerly sole issuer participated in a RADV for the benefit year, and in the following benefit year, a new issuer enters the formerly sole issuer risk pool, HHS proposes 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. HHS notes that this approach is consistent with the policy established in the 2015 Payment Notice, specifying that each issuer's risk score adjustment (from RADV results) will be applied to adjust the plan's average risk score for each of the issuer's risk adjustment covered plans. 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.

HHS discusses in the preamble its policy of accounting for all outliers, whether negative or positive and its impact on other issuers. HHS notes that its long-standing policy has been to account for identified risk differences, regardless of the direction of those differences. Except for the proposal described above for negative error rate outliers issuers exiting a state's markets, HHS proposes that no further changes are needed to the outlier adjustment policy or error estimation methodology even though 2016 results suggest a large number of negative error rate outliers. **HHS is, however, interested in feedback on the impact of the current error estimation methodology and the outlier adjustment policy for 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 create, and potential changes to those policies, for example, to use 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.**

g. Exemptions from RADV (153.630(g))

HHS proposes to codify three exemptions from RADV that have been established in previous rules or guidance. These exemptions are for smaller issuers or issuers entering liquidation. They have been provided to address concerns about the regulatory burden and costs associated with the RADV program. For a given benefit year, the following issuers would be exempt from RADV:

- The issuer has 500 or fewer billable member months of enrollment in the individual, small group and merged markets for the applicable benefit year, calculated on a statewide basis beginning with the 2017 benefit year of RADV;
- The issuer is at or below the materiality threshold as defined by HHS and is not selected to participate in the data validation requirements in an applicable benefit year under the random and targeted sampling conducted every 3 years (barring any risk-based triggers) beginning with the 2018 benefit year of RADV;
- 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 one being audited. The issuer must provide a signed attestation of this status; must not be in a positive error rate outlier for the prior benefit year of RADV; and the state court must have issued an order of liquidation.

D. Part 155 – Exchange Establishment Standards and Other Related Standards

1. Definitions (§155.20)

HHS proposes to add definitions of "direct enrollment technology provider," "direct enrollment entity," and "direct enrollment entity application assister." It would replace the prior definition of "web-broker" with a definition that distinguishes between web-brokers and other agents and brokers using a non-Exchange website to directly enroll consumers into a QHP. Discussion of some of those proposed changes are integrated below in sections summarizing §§155.220, 155.221, and 155.415.

A direct enrollment technology provider would be defined as a type of web-broker business entity that is not a licensed agent, broker, or producer under state law but has been engaged, created, or owned by an agent or broker to provide technology services to provide direct enrollment. HHS indicates that this definition is needed to identify entities that are not insurance agencies or brokerages but otherwise function as a web-broker. For example, these may include technology companies.

2. General Functions of an Exchange

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

In 2019, HHS allowed employers purchasing, and enrollees in, federally facilitated-State Health Options Program (FF-SHOP) coverage to enroll directly through issuers, agents and brokers registered with the federally-facilitated Exchange (FFE) instead of through the online FF-SHOP platform. Those FF-SHOPs were required to have in place a call center.

In this proposed rule, HHS would eliminate call center requirements for FF-SHOPs operating in this "leaner" fashion. Instead, those entering into a federal platform agreement in which HHS operates its eligibility ad enrollment functions or does not provide for enrollment through the SHOP platform but rather directly through plans, agents, and brokers would be required to have a toll-free hotline. HHS would also modify the requirements for such a hotline – eliminating the need to direct consumers to the HealthCare.gov to apply for and enroll in coverage through the Exchange. Instead the hotline would need to 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 resources.

The toll-free hotline would, under the proposal, need to be linked to interactive voice response capability, with prompts to pre-recorded responses to frequently asked questions, provide information about locating agents and brokers in the caller's area, and allow the caller to leave a message for additional information.

b. Navigator Program Standards (§155.210)

Under current law, each Exchange is required to have a Navigator program. Existing rules in §155.210(b)(2) require each Exchange to have a set of training standards that ensures expertise in the following areas:

- The needs of underserved and vulnerable populations;
- Eligibility and enrollment rules and procedures;
- The range of QHP options and insurance affordability programs;
- Privacy and security standards under §155.260;

In addition, Exchanges that require Navigators to provide assistance with a set of activities described in §155.210(e)(9) must also establish training standards for those activities. The activities authorized in §155.210(e)(9) include providing assistance with eligibility appeals and minimum essential coverage (MEC) requirements; reconciling tax credits; understanding basic

concepts and rights related to health coverage; and providing referrals to tax advisers, preparers or tax advice.

HHS proposes to retain training standards for the first four activities listed in §155.210(b)(2), but to eliminate the requirements for training standards for all of the optional Navigator activities described in §155.210(e)(9). HHS proposes to make a parallel change to Standards for Navigator and Non-Navigator Assistance Personnel in §155.215(b)(2) by eliminating the list of training topics and replacing the list with a reference to the amended §155.210(b)(2).

HHS notes that Exchanges may opt to provide more training than would be required under these proposed standards and that state-based exchanges would continue to have the flexibility to authorize their Navigators to provide those activities in all of the areas described §155.210(e)(9). HHS proposes to make these changes to increase flexibility in the design of Navigator training programs.

In the Regulatory Impact Analysis (RIA) section of the proposed rule, **HHS requests additional information to help it to quantify the burden reduction of these proposals. It is interested in the number of hours per month that Navigators spend providing assistance for activities in §155.210(e)(9); the percentage of their current work that is comprised of those activities; and what other activities Navigators might spend more time on if they were not required to do those listed in §155.210(e)(9).**

c. Ability of states to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs (§155.220)

As noted above, HHS proposes definitions for "direct enrollment technology provider," "direct enrollment entity," "direct enrollment entity application assister," and "web-broker." HHS notes that it uses the term web-broker to refer to an individual agent or broker (or groups or business entities of agents or brokers) that register with an Exchange to develop and host a direct-enrollment, non-Exchange website. A direct enrollment technology provider would be 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.

HHS proposes a number of changes to §155.220 to conform to changes proposed in §155.221 and to streamline and consolidate requirements applicable to all direct enrollment entities including issuers and web-brokers into one regulation. Proposed changes include:

- Incorporating term "web-broker" in those requirements that should extend to web-brokers generally when agents or brokers are mentioned, including where appropriate, direct enrollment technology providers.
- Revising the section heading for §155.220 to include web-brokers in it.
- Adding a requirement in new §155.220(c)(3)(i)(K) that web-brokers must comply with applicable requirements in §155.221 when an internet website of a web-broker is used to complete the QHP selection.
- Adding a requirement in new §155.220(c)(3)(i)(L) prohibiting web-broker websites from recommending QHPs based on compensation that web-brokers receive.

- Requiring in §155.220 (c)(4)(i)(A) web brokers to provide HHS with a list of agents or brokers who use the web-broker's non-Exchange website to assist consumers with QHP selection or Exchange application. HHS is considering requiring quarterly or monthly submissions of name, state of licensure, and National Producer Number. It anticipates providing further guidance on the form and manner of these submissions and **invites comments on the frequency, manner and data elements for the submissions**.
- Exempting those licensed agents or broker entities registered with the FFE as a business entity (rather than individual brokers or agents) and direct enrollment technology providers from the existing requirement in §155.220(d)(2), that agents and brokers receive training in the range of QHP options and insurance affordability programs. HHS states that this change is necessary because certain requirements make sense as applicable to individuals but not as applied to business entities.
- Modifying §155.220g(3) to add a provision allowing HHS to immediately terminate an agent's or broker's agreement with the FFE for cause with notice if appropriate licensing under all states in which the agent or broker is assisting Exchange enrollees isn't maintained.

HHS proposes additions to improve information technology (IT) system security in FFEs and SBE-FPs. Proposed new §155.120(k)(3) would permit HHS to immediately suspend an agent or broker's ability to transact information with the Exchange if HHS discover circumstances that pose unacceptable risk to Exchange operations or IT systems. Proposed new §155.220(m) would allow for a web-broker's agreement to be suspended or terminated based on the actions of its officers, employees, contractors, or agents, including if it is under common control or an affiliated business of another web-broker whose contract was suspended or terminated. Under the amendment, an Exchange would be permitted to collect identification information from a web-broker on its corporate owners and leaders.

HHS also proposes to allow Navigators and certified application counselors (CACs) to use web-broker websites to assist with plan selection and enrollment, to the extent permitted by state law. HHS discusses the promise of web-brokers developing portals that would enable real-time access to plan, eligibility, and enrollment information as well as its hope that collaboration between such assisters and web-brokers will encourage development of new tools to serve consumers. HHS reviews existing standards applicable to Navigators and CACs. In addition to those standards, HHS proposes several requirements for web-brokers' websites in order for assisters to be able to use them for an Exchange application or QHP selection and enrollment:

- They must display all QHP data provided by the Exchange consistent with existing §155.205(b)(1) and (c). (Those provisions require standardized comparative information on available QHPs in a language and manner that is accessible and timely.)
- If the web-broker doesn't facilitate enrollment in all QHPs, the website must identify the QHPs that it doesn't offer enrollment into by displaying a standardized disclaimer that would be provided by the exchange and display a link to the Exchange website. HHS expects to provide additional guidance on this disclaimer. **HHS invites comments on what requirements should be adopted for the disclaimer how it should be displayed on a web-broker's website.**
- The Exchange may require an annual certification process.

Exchanges may provide certification that these standards are met, but the proposed rule does not require such certification – only that the standards are met. **HHS also seeks feedback on the extent that web-broker websites, when used by assisters should be prohibited from making plan recommendations or reflecting preferences for certain plans.**

d. Standards for Direct Enrollment Entities and for Third Parties to Perform Audits of Direct Enrollment Entities (§155.221)

As direct enrollment advances and consumers are provided with more comprehensive services through non-Exchange websites, HHS proposes to streamline and consolidate regulatory requirements. In the past, direct enrollment regulations were separate for QHP issuers participating in direct enrollment and web-brokers. HHS states that with enhanced direct enrollment activities, requirements for those two different types of participants have become increasingly similar. In response, HHS proposes to revise §155.221 to apply the requirements in this section to all direct enrollment entities and to add additional requirements. Specifically, HHS proposes to:

- Revise the section heading from "Standards for Third-party Entities to Perform Audits of Agents, Brokers, and Issuers Participating in Direct Enrollment" to "Standards for Direct Enrollment Entities and for Third Parties to Perform Audits of Direct Enrollment Entities."
- Require third party entities that conduct annual reviews of direct enrollment entities to demonstrate operational readiness be independent of the entities they are auditing. Prior rules required only disclosure of these relationships. HHS notes that the disclosure would remain in regulations because an auditor may maintain an auditing contract with the entity it is auditing. HHS would further clarify that operational readiness must be demonstrated before the website may be used to complete an Exchange application or make a QHP selection.
- Add a new requirement that a written agreement must be executed between the direct enrollment entity and its auditor that is compliant with the standards of this section.
- Would identify in proposed revisions to §155.221(a) the types of entities that FFEs will permit to provide direct enrollment as non-Exchange websites, QHP issuers, and web-brokers that comply with all applicable provisions.
- Require direct enrollment entities to display and market QHPs and non-QHPs on separate web pages and to prominently display a disclaimer to help consumers distinguish between pages that display QHPs and those that display non-QHPs.
- Require that Exchange eligibility applications and the QHP selection process must be free from advertisements for non-QHPs.

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

a. Allowing Issuer Application Assisters to Assist with Eligibility Applications (§155.415)

HHS proposes to allow direct enrollment entities to contract with application assisters such as Navigators and CACs. Such "direct enrollment entity application assisters" would be defined as

an employee, contractor, or agent of a direct enrollment entity who is not a licensed agent, broker or producer under state law who assists individuals applying for eligibility or coverage through an Exchange for insurance affordability programs. Under the proposed revisions, existing rules for insurance application assisters would apply to direct enrollment application assisters including state licensure requirements. Section 155.415 would be further revised to authorize an exchange to permit assisters to provide assistance with applying for coverage and for insurance affordability programs.

Other existing standards would be applied to direct enrollment technology providers: entities using such assisters must ensure they comply with existing standards, receive training on QHP options, and have credentials to access FFEs and offer assistance with them. They must complete annual registration and training and comply with all applicable state laws related to the sale, solicitation, and negotiation of health insurance products including any state licensure laws. QHP issuers that use direct enrollment entities would also be subject to these requirements. Finally, HHS would clarify that direct enrollment entities participating in FFEs and SBE-FPs would be permitted to use application assisters to the extent permitted by state law.

b. Special Enrollment Periods (§155.605)

HHS proposes to allow Exchanges the option to provide for a new special enrollment period for individuals enrolled in non-Exchange plans in the individual market to enroll in an Exchange plan if they experience a decrease in household income and receive a new determination of eligibility for a premium tax credit by an Exchange.

Under the proposal, regular prospective coverage effective dates would apply, and an individual would be required to enroll within 60 days of the financial change. Individuals qualifying for the new special enrollment period would be required to provide evidence of both a change in household income and of prior coverage.

The new special enrollment period would be subject to existing rules in §155.605(a)(4)(iii) limiting the plans into which an enrollee who qualifies for a special enrollment period can enroll. If members of his or her household are already in an Exchange plan and they don't qualify for this special enrollment period, then the individual who does may join the family members' plan if the plan's business rules allow. If not, then the enrollees must be permitted to change to another QHP within the same level of coverage in order to add the newly qualified individual.

HHS also proposes to add to the types of coverage that can be considered prior coverage for the purpose of satisfying a prior coverage requirement to include Medicaid on the basis of pregnancy, Medicaid medically needy, and CHIP unborn child coverage.

In the RIA, HHS estimates that 4,700 new consumers would use this special enrollment period each year. The average length of enrollment would be for a period of 6 months. As a result, premium subsidies would be expected to increase by an estimated $15.3 million each year.

4. Eligibility Standards for Exemptions (§155.605)

a. Eligibility for an exemption through the IRS (§155.605(e))

Consistent with existing guidance[6], HHS proposes to codify the ability of the Internal Revenue Service (IRS) to provide a general hardship exemption from minimum essential coverage requirements. The IRS may already, through the tax filing process, provide for most other types of hardship exempts but not for the general hardship described in paragraph §155.605(d)(1). Under existing rules, individuals applying for those types of exemptions must do so through an Exchange. This provision would apply only to the 2018 tax year.

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

Under existing law and rules, individuals must maintain minimum essential coverage unless they are exempt from the requirement because the coverage is unaffordable. Affordability is determined based on whether the amount that he or she is required to pay for the coverage exceeds a required contribution percentage of his or her household income. Section 5000A of the Internal Revenue Code established that the required contribution percentage was 8.0% for 2014. For years after 2014, the required contribution percentage is indexed by the percentage that reflects the excess of the rate of premium growth between the preceding calendar year and 2013 over the rate of income growth for the period.

For 2020, HHS proposes to calculate premium growth differently than in past years by incorporating in the premium growth estimates, the growth of individual market insurance premiums as described in more detail below.

Although the Tax Cuts and Jobs Act (P.L. 115-97) reduced the individual shared responsibility payment to zero beginning after December 31, 2018, the required contribution percentage is still used to determine whether individuals over age 30 qualify for an affordability exemption that would allow them to enroll in catastrophic coverage.

HHS calculates premium growth using the "premium adjustment percentage" based on projections of average per enrollee employer-sponsored insurance premiums calculated by the HHS Office of the Actuary for the National Health Expenditures Accounts (NHEA). As described in past Payment Notices, for its measure of income growth, HHS uses NHEA projections of personal income.

The 2020 premium adjustment percentage is estimated to be 29.7% for the 2013 to 2019 period, which HHS indicates is 3.6% higher than the 2019 figure. HHS notes that this year's figure is not identical to past year's premium measures because this year HHS proposes to incorporate individual market insurance premium growth in the premium growth measure. The estimate of income growth using personal income estimates is calculated to be about 23.66% for the 2013-2019 period (or about 2.5% over the estimate of income growth used for the 2013-2018 period).

[6] September 12, 2018 "Guidance on Claiming a Hardship Exemption through the Internal Revenue Service (IRS). https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf.

As a result, HHS estimates the required contribution percentage for 2020 to be 8.39%, which reflects an increase of about 0.09 percentage points from 2019.

$$8.00\% \times 1.296721275/1.236613610 = 8.39\%$$

E. Part 156 – Health Insurance Issuer Standards under the ACA, Including Standards Related to Exchanges

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

HHS proposes a 2020 user fee for all participating FFE issuers of 3.0%, a percentage that is lower than the 3.5% in place for earlier years. For states electing to use the Federal Platform for Exchange functions (in which a state chooses use the federal IT platform for certain Exchange functions), HHS proposes a user fee for 2020 of 2.5%, an amount that reflects the proportion of FFE costs associated with FFE information technology infrastructure, the consumer call center, and eligibility and enrollment services. That rate is lower than the final user fee rate for 2019 for the Federal Platform for Exchange functions.

In its RIA, HHS estimates that user fees will increase transfers from SBE-FP issuers to the federal government by about $10 million for 2020.

2. Silver Loading

HHS states that it supports a legislative solution to the lack of appropriated funds for cost-sharing reduction payments. If an appropriation were provided, the practice of silver loading (where issuers incorporate the costs of cost-sharing reductions into premiums for silver metal level plans) would no longer be needed. **It seeks comment on ways that HHS might address silver loading for potential action in future rulemaking.**

3. Essential Health Benefits Package

a. State selection of EHB-benchmark plan (§156.111 and §156.115)

Beginning with plan year 2020, states have additional choices for its selection of their EHB-benchmark plans. The new choices, identified in §156.111, were finalized in the final 2019 Payment Notice. In addition to the prior options for a state's benchmark,[7] states may:

- Select a benchmark plan that another state used for the 2017 plan year (§156.111(a)(1));
- Replace one or more EHB categories of benefits used for the 2017 plan year with the same categories of benefits from another state's EHB-benchmark plan used for the 2017

[7] (1) The largest health plan by enrollment in any of the three largest small group insurance products by enrollment in the state's small group market; (2) Any of the largest three employee health benefits plan options by enrollment offered and generally available to state employees; (3) Any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options; (4) The coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the state.

plan year. A state can, for example, select prescription drug coverage from another state's benchmark that provides for a different formulary. HHS states that this option will allow states to make targeted changes to specific categories of benefits. (§156.111(a)(2)); and
- Select a set of benefits that will become the state's benchmark plan (§156.111(a)(3)).

In this proposed rule, HHS notes that it believes the third new option, selecting a set of benefits for the state's benchmark, provides opportunities for states to address the opioid epidemic. For example, Illinois made changes to its EHB to add alternative therapies for chronic pain, restricted access for opioids, and expanded coverage of mental health and substance use disorder treatment.

In addition, HHS proposes the following deadlines for states to submit documents for a state's EHB-benchmark plan selection for the 2021 and 2022 plan years. HHS recommends that states submit applications at least 30 days before the submission deadlines to ensure completion and reminds states that the period of public comment must also be completed by the deadlines.

The same deadlines apply to notification by states that they will permit issuers to substitute benefits between EHB categories. The deadlines are:

Proposed deadlines for submission of required documents for EHB-benchmark plan selection & to Notify HHS that issuers may substitute benefits between categories	
Plan year 2021	May 6, 2019
Plan year 2022	May 8, 2020

b. Prescription Drug Benefits (§156.122)

HHS solicits comments on prescription drug benefit policies. First, HHS asks whether therapeutic substitution and generic substitution policies should be pursued, whether certain categories of drug classes are better suited for such policies, and whether there are existing standards of practice for such policies that are nationally recognized and readily available for providers. In addition, HHS seeks comment on reference-based pricing including the opportunities and risks of implementing or incentivizing reference-based pricing.

c. Prohibition on Discrimination (§156.125)

HHS discusses the coverage of Medication-Assisted Treatment (MAT) for opioid use disorder and notes that while most QHP issuers cover MAT, inclusion on a plan's formulary does not necessarily ensure coverage. HHS encourages all plans to provide comprehensive coverage of MAT and to take every opportunity to address opioid use disorder.

HHS also reminds issuers that any reduction in the generosity of a benefit for subset of individuals that is not clinically indicated and does not comprise reasonable medical management is potentially discriminatory under the non-discrimination provisions. If a plan excludes coverage for certain treatments of opioid use disorder but covers the same treatment for

other medically necessary purposes, the issuer must be able to justify the exclusion with supporting documentation explaining how such a plan design is not discriminatory.

Further, under the standards imposed by the Paul Wellstone and Pete Domenici Mental Health Equity Act of 2008[8], limitations cannot apply only to mental health or substance use disorder benefits or be more stringent in application to mental health or substance use disorder benefits as compared to coverage for medical and surgical benefits. Other statutes – for example under the Americans with Disabilities Act[9] and the Rehabilitation Act of 1973[10] prohibit discrimination against individuals who participate in or have completed substance use disorder treatment including MAT.

d. Premium Adjustment Percentage (§156.130)

The premium adjustment percentage, as described above, is used to calculate three parameters: the maximum annual limitation on cost-sharing, the required contribution percentage for individuals for minimum essential coverage (and used to determine eligibility for hardship exemptions), and the assessable payment amounts under sections 4980H(a) and (b) of the Code. As noted above, that percentage for 2020 is estimated to be 29.7%.

HHS proposes to incorporate in the calculation of the premium adjustment percentage, into the measures of premium growth, the growth of individual market premiums instead of only including the growth of premiums in the employer market for insurance. HHS notes that this approach was considered in 2015 but was not finalized because at the time the volatility of premiums in the new Exchange individual markets would likely distort the measure. Beginning with 2020, HHS will include an adjusted private individual and group market health insurance premium measure. It is based on published NHEA data and includes employer-based insurance, individual market health insurance both on and off exchanges, but excludes Medigap insurance and the medical portion of accident insurance.

HHS anticipates that by including the faster growing individual market premiums in this measure, and if Treasury and IRS adopt the policy as well, it would increase the premium adjustment percentage. Doing so would have the impact of raising the limit on beneficiary cost sharing, raising individuals' required contribution amounts, raising employer shared responsibility payment amounts, reducing premium assistance tax credits, and lowering federal spending for premium assistance tax credits. In addition, fewer individuals would qualify for premium assistance tax credits. HHS notes that this change would result in reduced Exchange enrollment which could further increase premiums for those individuals remaining in the individual market for insurance.

HHS states that its criteria for calculating the premium adjustment percentage, as described in the 2015 Payment Notice, is maintained – the calculation should be 1) comprehensive – taking into account health insurance coverage for the entire market; 2) available – the data for its calculation should be available timely for publishing in the annual notice of benefit and payment

[8] P.L. 110-343.
[9] P.L. 101-336.
[10] P.L. 93-112.

parameters; 3) transparent – the methodology should be easy to understand and predictable; and 4) accurate – the methodology should have a record of accurately estimating average premiums.

Using the premium adjustment percentage to calculate the maximum annual limitations on cost-sharing for 2020 would result in those amounts rising to $8,200 for self-only coverage and $16,400 for other than self-only coverage. This represents about a 3.8% increase over the amounts for 2019.

In the RIA, HHS provides additional estimates of the impact of the proposed change in the calculation of the premium adjustment percentage. Under the proposed approach, an enrollee's required contribution would be 8.39 percent. That amount would be 8.18 percent if HHS continued to use only employer-sponsored insurance premiums in the calculation for the 2020 benefit year. The proposed maximum annual limitation on cost sharing of $8,200 for self-only coverage would be $8,000 under the 2019 methodology. HHS estimates that the higher costs for enrollees under the proposal would result in 100,000 fewer Exchange enrollees. Table 16 of the RIA, as duplicated below, describes the estimated impacts of the proposed change:

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**

e. Maximum Annual Limitation on Cost-sharing for Calendar Year 2020

Under existing law and regulations, issuers must provide cost-sharing reductions for certain eligible individuals by offering plan variations with reduced cost-sharing, including reduced maximum annual limitations. Each year, HHS specifies an annual maximum limitation on cost-sharing. The Secretary then may adjust those cost-sharing limits to ensure that they do not cause the actuarial values of the health plans to not meet the levels specified in statute for enrollees with different income levels (73%, 87% or 94%). Using a process similar to the one used in the 2014 – 2019 Payment Notices, HHS finds that the maximum annual limitation on cost-sharing

for people with income between 200% and 250% requires additional adjustment – as it did in 2017, 2018, and 2019. The resulting adjusted maximums proposed for 2020 would be as follows:

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 reduction with income between 100 and 150% of FPL	$2,700	$5,400
Individuals eligible for cost-sharing reduction with income between 150 and 200% of FPL	$2,700	$5,400
Individuals eligible for cost-sharing reduction with income between 200 and 250% of FPL	$6,550	$13,100

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

(i) Cost sharing requirements for generic drugs.

HHS proposes to allow plans in the individual and group markets for insurance that cover both a brand prescription drug and its generic equivalent to consider the brand drug's coverage to not be included as an Essential Health Benefit (EHB). By including only the generic as EHB, the issuer would be permitted to exclude cost sharing amounts for the brand, to the extent they are above the amounts for the generic, from the annual limitation on cost sharing. Under this proposal, issuers would be able to impose annual and lifetime limits on brand name drugs and premium tax credits could not apply toward any portion of the premium attributable to coverage of brand name drugs that are not part of EHB. HHS says this proposed change would better balance consumer protection with incentives to use lower-cost drugs.

For a plan to implement this proposal, it would be required to have an exception process in place in accordance with rules at §156.122(c).

HHS is also considering an alternate proposal in which the issuer would be permitted to exclude the entire amount of cost sharing for the brand from counting toward the annual limit on cost sharing.

This proposal would become effective beginning with the 2020 plan year. **HHS seeks comments on the two alternatives. In addition, HHS requests feedback on any limitations that health insurance issuers' IT systems would face in implementing changes to the cost- sharing amounts that would count toward annual limitations; whether the federal rules should be subject to or preempt state laws; and whether an issuer not attributing cost sharing to the annual limitation under this approach should be considered an adverse coverage determination subject to the appeals processes under §147.136. Finally, HHS requests comment on whether these provisions should be mandatory rather than an option for issuers.**

(ii) Cost-sharing requirements and drug manufacturers' coupons.

HHS proposes, in new §156.130(h)(2) to exclude certain assistance from drug manufacturers toward the cost of drugs from counting toward the annual limitation on cost sharing. HHS describes the use of copay coupons and other assistance for beneficiaries from drug manufacturers to assist consumers with their copayment obligations. This assistance is sometimes used to encourage physicians and beneficiaries to choose more expensive brand name products when a less expensive generic or other alternative is available according to HHS.

Under this proposal, beginning with plan years starting on or after January 1, 2020, amounts paid toward cost-sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate their out-of-pocket costs for specific brand drugs that have a generic equivalent would not be required to be counted toward the annual limitation on cost sharing.

HHS seeks comment on this proposal including whether states should be able to decide how coupons are treated, whether issuers would have difficulty carving out direct support from calculations of copayments when a generic is available, on issuer's ability to differentiate between manufacturer coupons and coupons from other sources, the implementation date and whether implementation barriers exist, how other drug discount programs should be treated under this proposal, and whether the proposed policy should apply only to QHPs.

4. Segregation of funds for abortion services (§156.280)

HHS proposes to require QHP issuers that offer coverage of non-Hyde abortion services (abortion services beyond those necessary to save the life of the woman, or in the case of rape or incest) in one or more QHPs to also offer at least one "mirror QHP", beginning with plan year 2020. A mirror QHP would be required to offer identical coverage to one of the QHPs except that abortion services would be omitted. A QHP issuer would only need to offer one mirror QHP through each services area even if the issuer has multiple plans that offer non-Hyde services in an area. The QHP issuer would be permitted to determine the metal level for the mirror plan.

HHS provides an explanation of its authority to impose this proposal on QHP issuers**. In addition, feedback is sought on the following questions: How can Exchanges and Healthcare.gov differentiate between the QHPs and mirror QHPs, should HHS establish standards for QHP issuers using direct enrollment and agents and brokers using an internet website for enrollment to differentially display the two types of QHPs?**

In its RIA, HHS estimates that a total of 75 QHP issuers would be required to offer an additional 1,111 plans in 17 states and notes that the impact in each state would depend on applicable state laws.

HHS proposes additional conforming changes to §156.1230 to align with proposed changes discussed above regarding direct enrollment providers, and notes that it may propose changes to, or removal of quality reporting measures in future Annual Call Letters for the QRS and QHP enrollee surveys.

III. Collection of Information Requirements

HHS identifies those provisions in the final rule for which it estimates potential burden and that would require an information collection review and approval under the Paperwork Reduction Act of 1995. They are summarized in Table 13, which is reproduced below.

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.

The majority of the additional costs relate to proposals to require issuers who make mid-year formulary changes to provide notice to enrollees regarding those changes (§147.106(e)(5)(i)(A) and (B)). Other estimates are provided for the costs associated with a proposed notice to HHS when an issuer makes a mid-year formulary change (§156.122(d)(3)), proposed changes to the sample size for issuers participating in RADV audits (§153.630(b)), and the proposed addition of a new special enrollment period (§155.420).

IV. Regulatory Impact Analysis (RIA)

A. Statement of Need and Overall Impact

OMB has determined that this final rule is "economically significant" within the meaning of section 3(f)(1) of Executive Order 12866, because it is likely to have an annual effect of $100 million or more in any one year. Accordingly, HHS has prepared an RIA that presents the rule's cost and benefits.

HHS states that 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. HHS believes it would reduce regulatory burden and administrative costs for issuers and states, and would lower net premiums for consumers.

B. Impact Estimates of the Payment Notice Provisions and Accounting Table

In addition to the estimates for specific provisions summarized throughout this document, Table 14 (on page 251 of the public display copy) summarizes HHS' estimates of the proposals' qualitative impacts and estimated direct monetary costs and transfers for health insurance issuers. The annualized monetized costs in Table 14 reflect the following qualitative benefits of the proposed rule:

- Greater market stability from updates to the risk adjustment methodology.
- 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 certain duties permitted instead of 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.

HHS does not estimate, but addresses the impact of certain other provisions in Table 14 including increased costs to health insurers resulting from proposed changes to RADV sample sizes; and potential increased costs to issuers, Exchanges and the federal government for increased enrollment via the proposed new special enrollment period.

Regulatory Review Costs. HHS estimates that the cost of reviewing this rule is $107.38 per hour (wage and overhead for medical and health services managers), and that it will take approximately 1 hour to review the relevant portions of this rule that cause unanticipated burden. For each entity that reviews the rule, the estimated cost is $107.38. Therefore, HHS estimates that the total cost of reviewing this regulation is approximately $34,469 ($107.38 x 321 reviewers based on the number of unique comments received on the proposed rule).