Affordable Care Act: Notice of Benefit and Payment Parameters for 2022 (CMS-9914-P); Summary of Proposed Rule

December 4, 2020

On December 4, 2020, the Centers for Medicare & Medicaid Services of the Department of Health and Human Services (HHS) and the Department of the Treasury published the proposed Notice of Benefit and Payment Parameters for 2022 in the Federal Register. (85 Federal Register 78572). The Notice of Benefit and Payment Parameters (the "Payment Notice") proposes to recalibrate risk adjustment models and implement several improvements, to enact direct enrollment flexibilities for states and to add flexibility to certain special enrollment periods. It would establish payment parameters for 2022 including user fees, premium adjustment percentages, and cost-sharing minimums and maximums. It proposes reporting requirements for pharmaceutical benefits managers (PBMs) and codifies policies for reporting temporary premium adjustments for risk adjustment programs and medical loss ratios (MLRs).

Comments are due on December 30, 2020. The Payment Notice is accompanied by the release of the draft Letter to Issuers in the FFEs[1] and the Draft 2022 Actuarial Value Calculator and Proposed Qualified Health Plan (QHP) Plan Year 2022 Data Submission and Certification Timelines.[2]

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[1] Available at 2022 Draft Letter to Issuers in the Federally-facilitated Exchanges (cms.gov).
[2] Available at Regulations and Guidance | CMS.

I. Summary of Major Provisions

Summary of Final 2021 and Proposed 2022 Parameters: Selected Provisions		
Provision	**Final 2021 Plan Year**	**Proposed 2022 Plan Year**
Required contribution percentage for exemption from mandate	8.27%	8.47%
Annual enrollee out-of-pocket cost-sharing maximum	$8,550/$17,100*	$9,100/$18,200*
Reduced out-of-pocket cost-sharing maximums at specified percentages of the federal poverty level (FPL)		
• 200-250% of FPL	$6,800/$13,600*	$7,250/$14,500*
• 150-200% of FPL	$2,850/$5,700*	$3,000/$6,000*
• 100-150% of FPL	$2,850/$5,700*	$3,000/$6,000*
Risk adjustment program annual user fee (per billable enrollee)	$3.00	$3.00
Federally Facilitated Exchange user fee	3.0% of premium	2.25% of premium
State-based Exchange with Federal Platform (SBE-FP) user fee	2.5% of monthly premium	1.75% of monthly premium
* Amounts for out-of-pocket limits and deductibles presented as "single policy/family policy."		

Risk Adjustment Program. Would recalibrate parameters and propose changes to risk adjustment models: adding two-stage specification in adult and child models to improve prediction at the low and high ends of expected spending and modifying enrollment duration factors in adult models. It would also permit states to request multi-year state risk adjustment transfer reductions.

Direct Enrollment Option. Would permit a state exchange on the federal platform or a FFE state to implement a direct enrollment option instead of centralizing enrollment via Exchanges. Under the option, consumers would apply and enroll in a qualified health plan (QHP) and receive a determination of eligibility for premium tax credits and cost-sharing reductions through the websites of QHP issuers and web-brokers.

Pharmaceutical Data Collection. Would require and specify pharmaceutical data that pharmacy benefit managers (PBMs) and QHP issuers would be required to submit to HHS.

Medical Loss Ratio. Would define prescription drug rebates and other price concessions that issuers must deduct from incurred claims for medical loss ratio (MLR) reporting and rebate calculations. Would allow issuers to prepay a portion or all of the estimated MLR rebates for a given MLR reporting year and clarify MLR reporting and rebate requirements for issuers that choose to offer temporary premium credits when permitted by HHS.

Web-broker and QHP Operational Readiness. Would codify additional detail for operational readiness reviews that are a prerequisite to web-brokers' non-Exchange websites to be used by consumers for Exchange eligibility applications or QHP selections.

Special Enrollment Periods. Would require enrollment verification for at least 75% of new enrollments through SEPs and add flexibility for individuals who qualify for a SEP because they no longer are eligible to receive advance payments of the premium tax credit (APTC).

II. Background

HHS reviews the statutory and regulatory history related to the implementation of the Exchanges and related topics. HHS sought advice from stakeholders on policies related to the operation of Exchanges and premium stabilization programs, and considered this input in developing the policies in the proposed rule. It solicited input from states on topics including risk adjustment and the proposed direct enrollment option for FFEs and state Exchanges. It also consulted with the National Association of Insurance Commissioners, and held meetings with Tribal leaders, issuers, trade groups, consumer advocates and employers.

III. Provisions of Proposed HHS Notice of Benefit and Payment Parameters for 2022

A. Part 147 –Requirements for the Group and Individual Health Insurance Markets

CMS proposes several technical changes to §147.104 (Guaranteed Availability of Coverage) to align with policies that are explained below. The changes would:

- Incorporate by reference certain special enrollment periods (explained below) ensuring that they apply both to coverage offered inside of and outside of Exchanges, and
- To clarify that special enrollment periods relating to errors of an Exchange do not apply outside of Exchanges.

B. Part 150 – CMS Enforcement in Group and Individual Markets

CMS proposes to make the following substantive and technical changes to Part 150:

- Replace references to "HIPAA" with "PHS Act" to clarify that the enforcement processes described in this part enforce HIPAA as well as other subsequent statutory changes to the Public Health Service Act (PHSA).[3]
- Make procedural changes to align administrative hearings with Departmental Appeals Board current practices to:
    - Remove requirements to file submissions in triplicate and instead permit electronic filing.
    - Permit video conferencing as a form of administrative hearing.

[3] HIPAA refers to the Health Insurance Portability and Accountability Act of 1996. That legislation established certain requirements in the PHSA applicable to health plans in the individual market for health insurance. The Affordable Care Act built on and added to those provisions.

- Update §150.431 to allow the Administrative Law Judge to communicate the next steps for a hearing in either the acknowledgement of a request for hearing or on a later date.

Parallel amendments are proposed to the administrative hearing requirements under subpart J of part 156.

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

1. 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 of 45 CFR Part 153. In brief, the risk adjustment program transfers funds from non-grandfathered plans in the individual and small group markets (within 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, HHS is operating risk adjustment in every state and did not receive any applications from states to operate risk-adjustment for the 2022 benefit year.

(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 risks 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 (starting with the 2017 benefit year) and prescription drug utilization factors (RXCs) (starting with the 2018 benefit year). Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children or infants is multiplied by a cost-sharing reduction (CSR) 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.

Risk Adjustment Model Recalibration (§153.320). HHS proposes changes to recalibrate risk adjustment models consistent with the methodology used for the 2021 benefit year using only enrollee-level EDGE data rather than a combination of EDGE and MarketScan data.[4] For

[4] For 2021, HHS transitioned to using three years of actual claims level data submitted by states through EDGE servers (which refers to distributed data computing environments) as opposed to past years in which HHS had to rely on one or more years of data from a research database (MarketScan) for risk adjustment modeling.

2022, instead of using the three most recent benefit years of enrollee-level EDGE data, HHS proposes to again use 2016, 2017 and 2018 enrollee-level EDGE data (as were used for 2021).

In past years, updating to the newest three-year period of enrollee-level EDGE data has resulted in HHS being unable to provide risk adjustment coefficients for the upcoming benefit year in the proposed rule because the most recent year's data were unavailable at the time of publication. In response to stakeholders' comments in past years, HHS proposes to not update to the three most recent years and instead continue to use 2016 through 2018 data. In doing so, HHS can provide the risk adjustment coefficients for the upcoming benefit year earlier, permitting issuers to have more time to incorporate this information into pricing their plans for the 2022 plan year.

Draft coefficients based on 2016, 2017 and 2018 enrollee-level EDGE data are presented in Tables 1 through 6 of the proposed rule. The coefficients incorporate other risk adjustment proposals that are described below. HHS notes that to the extent that one or more of those proposals are not finalized, the model coefficients could change.

Risk Adjustment Model Updates (§153.320). HHS proposes two model updates to the risk adjustment model for the 2022 benefit year and proposes to continue the market pricing adjustment for Hepatitis C drugs as has been in place since the 2020 benefit year. The two proposed model updates would improve prediction at the low and high ends of the spending distribution in both adult and child models and improve the enrollment duration factors in the adult model. They are described below. Proposed risk adjustment model factors incorporating all model changes are shown in Tables 1 through 6 in the proposed rule.

- *Improve Prediction at Low and High Ends of Expected Spending*. HHS reviews its concern, expressed in prior years that the HHS-HCC models underpredict plan liability for enrollees without HCCs and underpredict plan liability for enrollees with the highest HCC counts. It reviews the options that it considered to address these weaknesses.

  The approach that HHS proposes to incorporate in the 2022 benefit year model is a two-stage specification combined with the addition of interacted HCC counts factors. The first stage of the two-stage specification would involve a linear regression of simulated plan liability on age-sex factors and payment HCC factors for the adult and child models, with the addition of the enrollment duration and RXCs factors for the adult models. The second stage would use the reciprocal of prediction as weights from the first step as a second stage linear regression. To stabilize the weights from the first stage predictions, HHS would apply lower and upper bound caps on the predictions at the 2.5^{th} and 97.5^{th} percentiles in the adult models and the 2.5^{th} and 99.5^{th} percentiles in the child models.

  The two-stage specification would be combined with the severity and transplant indicators from the interacted HCC counts factors. For the severity indicator group, HHS would add separate count factors for one to 10+ payment HCCs for the adult

models and one to 5, 6 or 7, and 8+ payment HCCs for the child models. For transplant HCCs, HHS would incorporate variables for 4 to 8+ payment HCCs for the adult models and one variable for 4+ payment HCCs for the child models. All variables, including the severity and transplant indicators interacted in the interacted HCC counts factors, would be included in both stages of the regressions. The HCCs that flag the severity indicator and the transplant indicators are listed in Table 3.

HHS requests comment on the HCCs selected for the severity and transplant indicators, whether these changes should be incorporated for the 2022 plan year, whether the two changes should be transitioned in one year at a time, or whether the two-stage specification and the HCC count changes should both be delayed until the 2023 plan year.

- *Enrollment Duration Factors.* HHS reviews its concern expressed last year that the current enrollment duration factors underpredict plan liability for partial year adult enrollees with HCCs and overpredict plan liability for partial year adult enrollees without HCCs. It noted that last year, it declined to make changes, instead waiting for an additional year of enrollee EDGE data to examine this concern. After an additional year of experience, these weaknesses were still found to be present.

  In response HHS proposes, beginning with the 2022 benefit year, to remove the current 11 enrollment duration factors of up to 11 months for all enrollees in the adult models, and add new monthly enrollment duration factors of up to 6 months to the adult models that would only apply for enrollees with payment HCCs. If finalized as proposed, this would mean there would be no enrollment duration factors for adult enrollees without payment HCCs starting with the 2022 benefit year adult models. In addition, HHS would continue to include enrollment duration factors only in the adult models. **Comments are sought on whether these changes should be delayed until the 2023 benefit year and whether enrollment duration factors of different lengths should be considered.**

Cost-sharing Reduction Adjustments. Also consistent with prior years, cost-sharing reductions would be 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. For Massachusetts, HHS proposes to continue to use a cost-sharing reduction factor of 1.12 for all Massachusetts wrap-around plans.

Model Performance Statistics. 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. HHS publishes the proposed R-squared statistics for each model and benefit year separately in Table 8.

(b) Calculation of Plan Average Premium and State Average Premium Requirements for Extending Future Premium Credits

In response to COVID-19, HHS adopted temporary relaxed enforcement of a series of rules related to premium assistance to promote continuity of coverage during the 2020 COVID-19 Public Health Emergency (PHE). HHS proposes to specify how such temporary premium credits permitted during this and future emergencies would be treated for the state payment transfer formula. For plan year 2021 and beyond, should HHS retain or again adopt such flexibilities, and where a state provides for temporary premium credits, the plan average premium and statewide average premium used in the risk adjustment calculations would be calculated incorporating those temporary adjusted premium amounts. In addition, the reduced actual premiums for which plan enrollees are responsible for would be the amounts used in the calculations under the state payment transfer formula to reflect temporary premium credits. HHS would use the adjusted plan premiums incorporating the temporary credits when calculating transfers under the state payment transfer formula for the 2022 benefit year and beyond.

2. Overview of the Risk Adjustment Transfer Methodology (§153.320)

HHS proposes to continue the payment transfer formula finalized in the 2021 payment notice and to continue to use the same administrative cost reduction to the statewide average premium and high-cost pool factors. The statewide average premium will be reduced by 14 percent for administrative costs for the 2022 benefit year. The high-cost risk pool parameters are maintained with a threshold of $1 million and a coinsurance rate of 60 percent for benefit year 2022.

HHS proposes to apply the same administrative cost reduction to the statewide average premium and high cost factors for the 2022 benefit year and thereafter and therefore, instead of needing to specify the applicable methodologies and factors in the annual notice of benefit and payment parameters, it proposes to instead specify any changes to the risk adjustment methodology in notice and comment rulemaking published in advance of the applicable benefit year. It would incorporate this procedural change in new §153.320(c).

The state payment transfer formula, the formula that determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment, is reviewed. 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 reviews its policy of 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. HHS chose to use the statewide average premium and normalize the risk adjustment state payment transfer formula to reflect state average factors so that each plan's enrollment characteristics are compared to the state average and the calculated payment amounts equal calculated charges in each state market risk pool. Thus,

each plan in the risk pool receives a risk adjustment payment or charge designed to compensate for risk as compared to a plan with average risk in a budget-neutral manner.

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

In the 2019 Payment Notice (83 *FR* 16930), HHS provided to states, starting with the 2020 benefit year, 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 need for states to operate 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 accordance with existing §153.320(d)(2), 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 affected benefit year.

2022 Flexibility Requests. For the 2022 benefit year, HHS received a request from Alabama to reduce risk adjustment transfers by 50% for its small group and individual markets. HHS requests comments on this exception and notes that the documentation submitted by Alabama can be found posted under the "State Flexibility Requests" heading at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html.

Multi-Year State Flexibility Requests (§153.320(d)). Beginning with the 2023 benefit year, HHS proposes to permit states to request a reduction to its otherwise applicable risk adjustment state transfers for a period of up to 3 years. Stakeholders have requested this flexibility, and HHS states that it would promote greater predictability and stability and reduce the burden for those states. Consistent with existing rules for states requesting reductions, they would be required to submit evidence and analysis to demonstrate: (1) the state-specific factors that warrant the adjustment; (2) the percentage reductions to risk adjustment state transfers; and (3) a justification for the requested reduction or evidence demonstrating that the reduction would have de minimis impact on premiums. HHS would add that, for multi-year requests, the state would be required to confirm that it does not anticipate significant changes to the state market risk pools impacted and to respond to HHS requests for supplemental evidence in the form, manner, and time-frame specified by HHS.

In addition, HHS would be permitted to approve a shorter duration than the state requests if it determines that the supporting evidence and analysis do not support the requested duration. Further, HHS may request supplemental evidence at any time after initial approval and retains

the ability to terminate or modify a previously approved multi-year request if new data or information does not support its continuation. If a request is terminated or modified by HHS, the state must notify its issuers within 15 calendar days of the change.

4. Audits and Compliance Reviews

(a) Audits and Compliance Reviews of Issuers of Reinsurance-eligible Plans (§153.410(d))

In light of recent difficulties that HHS has experienced in auditing issuers of ACA transitional reinsurance-eligible plans, HHS codifies audit requirements, parameters and procedures to ensure that 2015 and 2016 benefit year audits may be completed. The proposed standards generally follow those set forth for compliance reviews of QHP issuers participating in FFEs (in 45 CFR 156.715) although these rules would apply to all reinsurance-eligible plans.

HHS would rename §153.410(d) "Audits and Compliance Reviews" and update introductory language to incorporate that reference. New paragraph (d)(1) would establish that HHS provide at least 15 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan. All audits would include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

Issuers would be required to:

- Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with an audit or compliance review;
- Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference; and
- Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, no later than 15 calendar days after the date of the request or inquiry.
- Where an issuer cannot provide the requested data or respond to HHS within the specified timeframes, the issuer may make a written request for an extension. The extension request must be submitted within the timeframe and detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

HHS would share its preliminary audit findings with the issuer, who would have 30 calendar days to respond in the format and manner specified by HHS. If the issuer does not dispute or otherwise respond to the preliminary findings, they would become final. If the issuer responds and disputes the preliminary findings, HHS would review and finalize its findings after the review.

The issuer would be required to comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and to (i) provide a written corrective action plan to HHS within 30 calendar days of the issuance of the final audit report, (ii) implement the corrective action plan and (iii) provide HHS with documentation of the corrective actions taken. If an issuer fails to comply with the audit activities set forth in this subsection in the manner and within the timeframes specified, HHS would notify the issuer of the amount of reinsurance payments received that the issuer has not adequately substantiated, and notify the issuer that HHS may recoup any payments that are not re-paid.

(b) Audits and Compliance Reviews of Issuers of Risk-adjustment Covered Plans (§153.620(c))

HHS proposes at §153.620(c) substantively identical audit and compliance provisions applicable to risk-adjustment covered plans as those described above applicable to reinsurance-eligible plans in.

5. EDGE Discrepancy Materiality Threshold

Under existing practice, issuers submit to HHS through their EDGE server data on enrollee-level enrollment, claims, and encounter data for a benefit year. HHS compiles the data and provides final EDGE server reports back to the issuer. An issuer must report any discrepancies it identifies. HHS then evaluates those discrepancies to determine if they would have a material impact on risk adjustment transfers in a state market risk pool. If so, HHS has a process to address the data submission. Currently HHS uses a materiality threshold of $10,000 – if the discrepancy is equal to or exceeds the lower of either $10,000 or one percent of total estimated transfers then it is considered material and is addressed.

HHS proposes to raise the materiality threshold and codify it in §153.710. The proposed materiality threshold would be an amount in dispute which is equal to or exceeds one percent of the applicable payment or charge payable to or due from the issuer for the benefit year, or $100,000, whichever is less.

6. Risk Adjustment User Fee for 2022 Benefit Year (§153.610(f))

HHS proposes a risk adjustment user fee for the 2022 benefit year of $0.25 per member per month (PMPM), the same amount as for the 2021 benefit year. Those amounts are based on the same methodology as used for 2021 and reflect a total cost of approximately $60 million to operate the program.

7. Risk Adjustment Data Validation Requirements (§153.630)

HHS conducts risk adjustment data validation (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 audit entity for the initial validation. 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. The second validation audit is conducted by an entity that HHS retains to verify the accuracy of the findings of the initial validation audit.

(a) Exemptions from HHS-RADV (§153.630(g))

HHS does not make changes to the exemptions from HHS-RADV that are currently permitted but codifies two exemptions that were previously established in the 2020 Payment Notice but not codified in §153.630(g). The two exemptions are for:

- An issuer which only offers small group market carryover coverage during the benefit year, and
- An issuer that is the sole issuer in the state market risk pool during the benefit year that is being audited and did not participate in any other market risk pools in the State during the benefit year that is being audited.

(b) Initial Validation Audit Requirements (§153.630(b))

HHS provides a clarification without a change to the regulatory text in §153.630(b). That existing provision requires that an initial validation entity must be impartial and free of conflicts of interest. HHS clarifies that in order to demonstrate that the entity is reasonably free of conflicts, it must also not have or previously had a role in establishing any relevant internal controls of the issuer related to risk adjustment or the EDGE server data submission process nor served as an advisor to the issuer regarding risk adjustment or EDGE server data for the applicable benefit year.

(c) HHS-RADV Administrative Appeals

HHS proposes to add the words "if applicable" to a provision permitting an issuer to appeal the findings of a second validation audit. The addition of this term reflects the fact that an issuer has a right to appeal the result of a second validation audit only if they receive a Second Validation Audit Findings Report – and only those issuers that have insufficient pairwise agreement between the initial and second validations receive such a report.

(d) Timeline for Collection of the HHS-RADV Payments and Charges

HHS proposes to revert to its prior schedule for collecting HHS-RADV charges and disbursing payments that was in place before the 2020 Payment Notice. In the 2020 Payment Notice, HHS had adopted a timeline that allowed issuers to report HHS-RADV adjustments in a later MLR reporting year and to incorporate guidance from state insurance departments in a later benefit year.

HHS explains that the existing timeline was intended to address stakeholder concerns about the predictability of HHS-RADV adjustments but stakeholders have instead stated that it has introduced unnecessary complexity and conflicts with other applicable timelines such as those required by states for financial accounting and negatively impacts issuers' MLR rebates.

HHS proposes to begin collection of 2021 HHS-RADV adjustments and default data validation charges and disbursement of such amounts in the summer or fall of 2023 (instead of later under the existing timeline) and to release the applicable benefit year's reporting on adjustment and default data validation charges earlier in the year so they are available for issuers to use for MLR reporting purposes. The applicable benefit year's HHS-RADV summary report would be released no later than early summer and issuers would be required to report those amounts in the MLR reports submitted by July 31st of the same calendar year in which the results are released.

HHS proposes to begin this policy with the collection and disbursement of HHS-RADV adjustments and default data validation charges for the 2019 benefit year. However, due to the delay in the 2019 benefit year HHS-RADV, the timing of collections and disbursements would be different for the 2019 benefit year. If finalized, HHS would publish the 2019 benefit year HHS-RADV Summary Report in early summer of 2022, and the 2020 benefit year HHS-RADV Summary Report in early summer of 2022. Issuers would be required to include any payments and charges reflected on these reports, along with risk adjustment transfers for the 2021 benefit year, in their 2021 MLR reports, which must be filed by July 31, 2022. Finally, HHS would begin collecting both 2019 and 2020 HHS-RADV adjustments to transfers along with any default data validation charges imposed for these two benefit years and disbursing related payments in late summer or early fall of 2022. Issuers would be required to report the 2019 and 2020 benefit year HHS-RADV adjustments to transfers in their MLR reports for the 2021 MLR reporting year.

HHS seeks comment on whether any consideration should be made in the transition to this policy to account for 2017 and 2018 benefit year HHS-RADV collection and disbursement of payments and charges (under the current timeline) also occurring in 2021 and 2022.

(e) Second Validation Audit and Error Rate Discrepancy Reporting Window

Under existing rules, an issuer must confirm the findings of a second validation audit or the calculation of a risk score error rate within 30 days of the notification by HHS of its findings. HHS proposes to amend this timeline to 15 days, and would apply the shorter timeframe starting with the 2020 benefit year HHS-RADV. HHS states that the shorter timeline will allow it to resolve as many issues as possible before publishing the Summary Report of RADV Adjustment to Risk Adjustment Transfers. It does not believe that the shortened window will be overly burdensome to issuers.

8. Risk Adjustment Data Reporting Requirements (§153.710)

Consistent with the proposal described above to include temporary premium credits offered during the PHE period in risk adjustment calculations, HHS proposes to modify risk adjustment data reporting requirements to require risk-adjusted covered plans that provide temporary premium credits to report to their EDGE servers premiums that incorporate any

temporary premium credits. The proposal would apply during future periods should HHS permit temporary credits. HHS describes the concerns it would have if plans did not report premiums that incorporate such reductions – including potential distortions in risk adjustment distributions across different plans.

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

1. Definitions (§155.20)

HHS proposes one new definition and several changes to existing definitions.

- Qualified health plan issuer direct enrollment technology provider is newly defined as a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment including a web-broker that provides services as a direct enrollment technology provider to QHP issuers. A QHP issuer direct enrollment technology provider that provides technology services or provides access to an information technology platform to a QHP issuer will be a downstream or delegated entity of the QHP issuer that participates or applies to participate as a direct enrollment entity. HHS says this definition is necessary to clarify that QHP issuers can engage such entities to assist with development and hosting of a non-Exchange website to facilitate the QHP issuer's participation in direct enrollment.
- Agent or broker direct enrollment technology provider. HHS proposes to rename "direct enrollment technology provider" as "agent or broker direct enrollment technology provider to distinguish it from the newly proposed definition of "qualified health plan issuer direct enrollment technology provider."
- A conforming change would also be made to the definition of "Web-broker" to replace a reference to "direct enrollment technology provider" with "Agent or broker direct enrollment technology provider".

HHS states that in this proposed rule, the term "Exchanges" collectively refers to all of the following models of Exchanges: State Exchanges, also called State-based Exchanges (SBEs); Federally-facilitated Exchanges (FFEs); State-based Exchanges on the Federal platform (SBE-FPs); and the new proposed Direct Enrollment (DE) Exchanges (FFE-DEs, SBE-FP-DEs, or SBE-DEs) (proposal is described below). When HHS refers to "the Exchange(s)" and "an Exchange," it is referring to Exchanges established and operated by a state (including a regional Exchange or subsidiary exchange) or by HHS. It does not describe what a "subsidiary exchange" means.

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

HHS proposes to make several changes to standardize the references to web-brokers by replacing all references in §155.205 to "an agent or broker subject to §155.220(c)(3)(i)" with the term "web-broker." It began to make these changes in earlier Payment Notices, but inadvertently missed some references.

In addition, HHS proposes changes to the timeline for QHP issuers and web-brokers participating in the Enhanced Direct Enrollment (EDE) program[5] to come into compliance with website content translation requirements. Under existing rules, they are required to translate website content into any non-English language that is spoken by a limited English proficient (LEP) population that makes up 10 percent or more of the total population of the relevant state. Web-brokers are required to do so within one year of registering with the Exchange and QHP issuers no later than the first day of the individual market open enrollment period for the 2017 benefit year.

Under the proposed rule, QHP issuers and web-brokers would have 12 months from the date that they begin operating their FFE-approved EDE website. This provision would have no impact on the timeline for complying with website content translation requirements for content that is unrelated to their participation in the FFE EDE program such as Summaries of Benefits and Coverage or provider directories. It would not impact other accessibility requirements such as oral interpretation services, telephone interpreter services, written translations or tagline requirements. It also would not affect QHP issuers or web-brokers approved to participate in the new proposed direct enrollment option (summarized below). Those entities must translate website content intended for consumers into any non-English language that is spoken by a LEP population that makes up 10 percent or more of the total population of the relevant state, as soon as the web-broker or QHP issuer begins operating in that state.

HHS seeks comments on whether the extended timeline for translation could impact access to Exchange coverage for LEP communities or negatively impact the operation of Exchanges; whether QHP issuers or web-brokers may be incentivized to invest in and expand into states with more LEP communities; and whether it provides sufficient time to encourage entry into states with 10 percent or greater LEP populations.

3. Navigator Program Standards (§155.210)

HHS proposes permitting Navigators and certified application counselors (CACs) in FFEs and SBE-FPs to use web-broker non-Exchange websites to assist consumers with applying for insurance affordability programs and QHP enrollment under certain circumstances (discussed below) and to the extent permitted by state law.

[5] Since 2019, QHP issuers and web-brokers are permitted to participate in enhanced direct enrollment (EDE). EDE is a way for consumers to apply for and enroll in health coverage though Federally-facilitated Exchanges (FFEs) and State-based Exchanges that use the Federal Platform (SBEFPs) without visiting HealthCare.gov. The new platform was established by HHS to improve the consumer experience in shopping for, applying for, and enrolling in Exchange coverage through third parties by allowing consumers to interact directly with private partners and complete all steps in the eligibility and enrollment process on a single website. See Enhanced direct enrollment FAQ (cms.gov).

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

(a) Navigator and Certified Application Counselor Use of Web-broker Websites

HHS proposes to lift its prohibition against Navigators and CACs from using web-broker websites to assist with QHP selection and enrollment. HHS notes that since EDE functionality has improved, stakeholders are increasingly expressing interest in using the EDE pathway to enroll consumers in Exchange coverage. The proposal would permit assisters in both FFEs and SBE-FPs to use web-broker non-Exchange websites to assist with QHP selection and enrollment so long as it is permitted under state law and if the website meets certain conditions:

- The website must display all QHP data provided by the Exchange related to all QHPs offered through the Exchange.
- If the website does not facilitate enrollment in all QHPs offered through the Exchange, it must identify all QHPs available to consumers by prominently displaying a standardized disclaimer provided by the Exchange, and in the manner and form specified by the Exchange, stating that enrollment in such QHPs can be completed through the Exchange website and provide a link to the Exchange website. HHS anticipates issuing further guidance on the disclaimer and invites comments on how it should be displayed.

In addition, under the proposal, a web-broker that makes its website available for use by Navigators and CACs, may complete a voluntary annual certification process with the Exchange. HHS would maintain a public list of approved web-brokers in FFEs or SBE-FPs.

HHS reviews applicable safeguards that would continue to apply to assisters and web-brokers under this proposal. For example, assisters must provide fair, accurate and impartial information and be free of conflicts of interest. Web-brokers may not display QHP recommendations based on the compensation the web-broker receives from QHP issuers, nor engage in marketing or conduct that is misleading, coercive, or discriminatory through their websites.

HHS expects that the proposal will encourage collaboration between assisters and web-brokers that will benefit consumers. It will also benefit assisters by allowing more collaboration with new partners and improve their ability to help consumers.

(b) QHP Information Display on Web-broker Websites

HHS proposes changes to the information that web-brokers are required to display on their non-Exchange websites to provide flexibility for web-brokers whose websites do not support enrollment in a QHP. Under existing rules, a web-broker non-Exchange website must disclose and display all QHP information provided by the Exchange or directly by QHP issuers or prominently display a standardized disclaimer provided by HHS that the QHP is available on the Exchange website. They must also provide a link to the Exchange website.

Under the proposal, except where the website of a web-broker is intended to be used by assisters, if the website does not support enrollment in a QHP offered through the Exchange, the web-broker is not required to provide all of the standardized comparative information for that QHP, but the web-broker's website must instead: prominently display a standardized disclaimer provided by HHS stating that the standardized comparative information for the QHP is available on the Exchange Web site; provide a web link to the Exchange website; and display the following minimum QHP information: issuer marketing name, plan marketing name, plan type, metal level, and premium and cost-sharing information.

(c) Web-broker Operational Readiness Review Requirements

HHS proposes new §155.220(c)(6) to establish a requirement for a web-broker to demonstrate operational readiness and to comply with certain requirements prior to its non-Exchange website being ready to complete an Exchange eligibility application or QHP selection. Under the proposal, the web-brokers must complete or submit: operational data including licensure information, points of contact, and third-party relationships; enrollment testing prior to approval or renewal; website reviews by HHS; security and privacy assessment documentation; and agreements between the web-broker and HHS.

5. Standards for, and Audits of Direct Enrollment Entities (§155.221)

(a) Display Requirements

HHS proposes to add clarifications and additional display requirements that would apply to enrollment entities that wish to display and market QHPs and non-QHPs. Under existing rules, those DE entities must display QHPs and non-QHPs on separate web-pages. Under the proposed rule, they would be required to display three sets of products on at least three separate web-pages subject to certain exceptions. The three categories of products that must be displayed separately are: QHPs offered through Exchanges; individual health insurance overage offered outside of Exchanges (can include both QHPs and non-QHPs); and all other products including excepted benefits.

Two exceptions to the above rule would be:

- For individuals who have an offer of an individual coverage health reimbursement arrangement. For those individuals, QHPs offered through the Exchange and other individual health insurance may be displayed and marketed on the same page. In this case the page must clearly distinguish between the QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange and prominently communicate that advance payments of the premium tax credit and cost-sharing reductions are available only for QHPs purchased through the Exchange. The page must also clearly state that advance payments of the premium tax credit are not available to individuals who accept an offer of an individual coverage health reimbursement arrangement, or who opt out of an individual coverage health reimbursement arrangement that is considered affordable. Finally, the page must note that a salary reduction

arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange.
- For the display and marketing of Exchange-certified stand-alone dental plans offered outside the Exchange and non-certified stand-alone dental plans.

(b) Operational Readiness Review Requirements

HHS proposes to add additional detail to the operational readiness requirements for direct enrollment entities similar to proposed requirements for web-brokers described above. Under the proposed rule, a direct enrollment entity must demonstrate operational readiness before its internet website could be used to complete an Exchange eligibility application or a QHP selection. To demonstrate readiness, it must submit or complete, in the form and manner specified by HHS, business audit documentation and security and privacy audit documentation.

(c) FFE, SBE-FP, and State Exchange Direct Enrollment Options (§155.221(j))

Beginning for plan year 2023, HHS proposes a new option for the federal Exchange and state Exchanges to implement direct enrollment via QHP health plan issuers or web-brokers in lieu of the centralized Exchange application and enrollment functions. HHS asserts that states are best equipped to adapt Exchange functions to local markets and the new options would provide for more flexibility and lower costs. HHS notes that the traditional Exchanges also face choke points when large numbers of consumers access them on high traffic days and those choke points inhibit access to enrollment. HHS further notes that Exchanges are unable to keep pace with innovation in e-commerce and to evolve based on the preferences of consumers.

Under the proposed rule, a state can elect the Exchange Direct Enrollment Option, subject to HHS approval, in addition to or in lieu of an Exchange operating its own (or a federally-facilitated) consumer facing eligibility application and enrollment website. The state could approve one or more enrollment entities to enroll qualified individuals in a QHP offered through the Exchange using a non-Exchange online website. The approved entities must be able to provide for applications using the eligibility verification and enrollment application described in existing §155.405, and receive the following from the Exchange: eligibility determinations for QHP enrollment, premium tax credits and cost-sharing reductions; and a determination of eligibility for Medicaid and CHIP.

A state Exchange choosing the Direct Enrollment Option must:
- Meet all federal statutory and regulatory requirements for the operation of an Exchange;
- Submit a revised Exchange Blueprint;
- Demonstrate operational readiness including readiness of the proposed direct enrollment entities to enroll qualified individuals into QHPs, to assist individuals in applying for and receiving eligibility determinations for QHP enrollment, advance payments of the premium tax credit and cost-sharing reductions, and to receive assessments or determinations of Medicaid and CHIP eligibility from the Exchange;

- Provide HHS with an implementation plan and timeline that details key activities, milestones, and communication and outreach strategy to support the transition to direct enrollment entities; and
- Ensure that at least one direct enrollment entity meets minimum federal requirements to participate in the FFE direct enrollment program, and is capable of enrolling all consumers in the State, including those who present complex eligibility scenarios. Where no direct enrollment entity approved by the State meets such minimum federal requirements or possesses the capability to enroll all consumers in the State, the State must offer a consumer-facing website that meets such requirements and possesses such capability.

A state with a Federally-facilitated Exchange or State Exchange on the Federal platform may also implement the direct enrollment option. To do so it must:

- Coordinate with HHS on an implementation plan and timeline;
- Execute a Federal agreement with HHS that includes the terms and conditions for the arrangement and defines the division of responsibilities between HHS and the State;
- Agree to procedures developed by HHS for the collection and remittance of the monthly user fee; and
- Perform and cooperate with HHS oversight and financial integrity requirements including reporting and compliance activities required by HHS and described in the Federal agreement.

6. Certified Applications Counselors (CACs) (§155.225)

As described above, HHS proposes to allow CACs to assist consumers with enrollment into QHPs and applying for eligibility for premium tax credits and cost sharing subsidies through web-broker websites under certain circumstances.

7. Verification Process Related to Eligibility for Insurance Affordability Programs

Under existing rules, in determining eligibility for a premium tax credit (APTC) or cost sharing reduction payments (CSRs), an Exchange must verify whether an applicant is eligible for or enrolled in an employer-sponsored plan using available data sources. If the Exchange does not expect to obtain sufficient verification data, then it may use an alternate procedure for such verification. The alternative, as described in §155.320(d)(4)(i) requires Exchanges to conduct a manual random sampling of applicants. Experience has indicated that employer response rates, however, are low and the process is burdensome for states, employers, consumer and taxpayers. Further, the value of the result tends not to outweigh the burden of the process because only a small percentage of sample enrollees have been determined to be receiving an APTC or CSRs in error.

HHS is conducting a study to determine why individuals with available employment-based coverage would seek coverage through Exchanges. The report, which is not yet complete, will compare costs for consumers and will help to inform future rulemaking regarding verification. In

the interim, HHS states that it will not take enforcement action against Exchanges that do not perform random sampling for plan years 2021 and 2022.

8. Special Enrollment Periods (§155.420)

(a) Exchange Enrollees Newly Ineligible for APTC

Existing rules at §155.420(a)(4) limit Exchange enrollees' ability to change QHP metal levels when they qualify for, or when a dependent newly enrolls in, Exchange coverage through special enrollment periods. These limitations were established to address concerns that enrollees could use special enrollment periods to change metal levels based on health care needs – a form of moral hazard which could impact risk pools. An existing special enrollment period exists for a person who becomes newly eligible or ineligible for advance payments of the premium tax credit, or experiences a change in eligibility for cost-sharing reductions, to enroll in coverage.

HHS proposes to add a new flexibility in §155.420(a)(4) to permit enrollees and their dependents who become newly ineligible for APTC to be able to enroll in a QHP of a lower metal level. It explains that some individuals may see their income rise (or household size shrink), which could lower their APTC by an amount that makes maintaining their existing plan unaffordable. To encourage more continuous coverage, the proposed rule would allow those individuals to choose a new lower metal level plan which would presumably be more affordable. This proposal is similar to the provision codified in the 2021 Payment Notice 85 FR 29204) to permit, beginning January 2022, enrollees and their dependents who are enrolled in a silver-level QHP and who become newly ineligible for CSRs to change to a QHP that is one metal level higher or lower than silver.

HHS notes that some individuals could lose APTC because of other reasons, for example they have not confirmed their income, or data matching has detected that they qualify for other affordable coverage. **HHS seeks feedback on whether the proposal could become a default for some individuals who do not understand that they simply need to provide additional documentation to retain their APTC and if the proposal could be improved if it only applied when the loss of APTC was due to a change in household income or family size.**

Comments are also sought on whether this provision should only permit an enrollee to change to a plan that is *one* metal-level lower than their current QHP (rather than any lower metal-level), whether it would be burdensome for Exchanges to administer, and whether it would increase adverse selection. HHS is also interested in feedback about whether it should consider additional flexibility to allow enrollees and their dependents who become newly eligible for APTC to change to a QHP of a higher metal-level.

(b) Untimely Notice of Triggering Event (§155.420(c)(5))

Because the time period during which a qualified individual is permitted to take advantage of a special enrollment period is limited, it is important that an individual learn of their triggering event in a timely fashion. HHS has found that there are circumstances in which an individual

doesn't learn about a triggering event until after their special enrollment period has ended. To address this issue, HHS proposes to allow a qualified individual, enrollee, or dependent who does not receive timely notice of a triggering event and was otherwise reasonably unaware that a triggering event occurred, to be able to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event. In addition, the Exchange must provide for such persons to choose the earliest effective date that would have applied for the triggering event. The provision would also apply in the off-Exchange market via a conforming amendment in §147.104(b)(2)(ii).

(c) SEP for Cessation of Employer Contributions to COBRA (§155.420(d)(1)(v))

Under the federal Exchange platform, a special enrollment period is provided to individuals who lose COBRA continuation coverage when a former employer's contributions to that coverage cease in whole or in part. State Exchanges and off-Exchange plans are not required to treat that scenario as a triggering event for a special enrollment period, however.

HHS proposes to establish for all Exchanges, that a special enrollment period be triggered when a qualified individual or dependent is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premium and those contributions cease. The proposal would align HHS' current policy with special enrollment for off-Exchange plans and for plans sold through state Exchanges.

An individual eligible for this SEP would have 60 days before or after the triggering event to select a QHP. HHS provides the following two examples of how this SEP would apply:

Example 1: An individual is laid off from a job in June, and enrolls in COBRA continuation coverage for which the employer pays 100 percent of the premiums (the employer does not require payment of a 2 percent administrative fee). On September 3rd of that year, the employer informs the individual that it is completely terminating contributions to the individual's COBRA continuation coverage as of September 30th, and beginning on October 1st, the individual will be responsible for 100 percent of the COBRA continuation coverage premiums. As a result, the individual decides to end COBRA coverage on October 1st. Because September 30th is the last day for which the individual had COBRA continuation coverage for which the employer was contributing, the individual has 60 days before and after this date (in this case, between August 1st and November 29th) to select an individual market plan through a special enrollment period.

Example 2: Same scenario as in the first example, except that the employer was paying only 25 percent of the COBRA continuation coverage premiums before the employer completely terminated contributions. The individual decides to maintain COBRA continuation coverage despite the loss of employer contributions. Even though the individual retained COBRA continuation coverage, the individual is still eligible to select a QHP through a special enrollment period from August 1st to November 29th, 60 days before or after the last day on which the individual had COBRA continuation coverage with employer contributions.

Comments are sought on whether HHS should permit a SEP where an employer reduces but does not cease their contributions to a COBRA continuation plan.

(d) Special Enrollment Period Verification (§155.420(f))

HHS proposes to add SEP verification requirements for state Exchanges. It notes that it did not establish such requirements previously to enable state Exchanges to have flexibility in the policies they adopt in this area, but to date all state Exchanges conduct either pre- or post-enrollment verification for at least one special enrollment type.

Under the proposed rule, unless the state has received approval from HHS to use an alternative process, an Exchange would be required to conduct verification of at least 75 percent of all special enrollment periods for individuals newly enrolling in Exchange coverage. If the Exchange is unable to verify eligibility for individuals newly enrolling in Exchange coverage through a SEP for which the Exchange requires verification, then the individuals are not eligible for enrollment. Existing appeals processes (in §155. 505b(iii)) would apply to individuals found to be ineligible.

9. 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 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 same period (referred to as the premium adjustment percentage.)

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.

For 2022, HHS proposes to use the same approach as for last year, incorporating the growth of individual market insurance premiums into overall premium growth estimates. For 2022, HHS proposes a premium growth estimate of 44.1%, which HHS indicates is 6.4% higher than the 2021 figure.

As described in past Payment Notices, for its measure of income growth, HHS uses National Health Expenditure Accounts (NHEA) projections of personal income. The estimate of income growth using personal income estimates is calculated to be about 36.1% for the 2013-2021 period (or about 3.9% over the estimate of income growth used for the 2013-2020 period).

Taking these factors into account, HHS calculates the 2022 premium adjustment percentage to be equal to 44.1% divided by 36.0% or about 1.059. As a result, the required contribution percentage for 2021 is equal to 8.0% multiplied by 1.059 or 8.47%, which reflects an increase of about 0.2 percentage points from 2020.

8.00% ×1.441/1.36 = 8.47%

Beginning with the 2023 benefit year, HHS proposes to publish the required contribution percentage, the premium adjustment percentage, and the annual cost sharing limitation parameters in guidance separate from the annual notice of benefit and payment parameters.

10. Excluding the Special Enrollment Period Trigger in §155.420(d)(1)(v) from Applying to SHOP Plans (§155.726)

HHS proposes to exclude the proposed special enrollment period due to cessation of employer contributions to COBRA continuation coverage from applying to SHOP plans as such plans are not available in the group insurance market.

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

1. User Fee Rates for the 2022 Benefit Year (§156.50)

HHS proposes to reduce the user fee rates for 2022 for all participating FFE issuers to 2.25 percent (from 3.0 percent) of premiums. This fee reflects the costs of certifying plans as QHPs, and selling coverage through the FFE for those determined eligible to enroll in a QHP. Other benefits that issuers receive via federal Exchanges are consumer assistance tools, consumer outreach and education, the Navigator program, regulation of agents and brokers, eligibility determinations, and enrollment processes. The reduction reflects, in part, the transition to include more direct enrollment.

For issuers offering coverage through state Exchanges using the Federal Platform for Exchange functions (in which a state chooses use the federal information technology platform for certain Exchange functions), HHS likewise proposes to reduce the user fee to 1.75 percent of premium for 2022 from the 2.5 percent charged for 2021. That amount reflects the proportion of FFE costs associated with FFE information technology infrastructure, the consumer call center, and eligibility and enrollment services.

Issuers offering plans through the new direct enrollment options (FFE-DE or SBE-FP-DE) available beginning in 2023 will benefit from consumer outreach, education and support activities. HHS proposes to charge a user fee rate of 1.5 percent of premiums in 2023. HHS seeks comment on this proposed rate including whether it should be state-specific, or should change based on the specific services that HHS will provide.

HHS proposes to eliminate a flexibility that it established in the 2017 Payment Notice wherein HHS would collect, if a state requested, an additional user fee to offset the costs to states' Exchange functions. The flexibility was added to reduce states' administrative burden, but HHS finds that it increases HHS' burden.

HHS proposes a clarification to §156.50(d) to make clear that issuers participating through SBE-FPs may receive certain adjustments to user fees for contraceptive claims that they have reimbursed. This conforms with changes made in the 2017 Payment Notice allowing state Exchanges to enter into agreements with the federal platform for these functions.

HHS seeks recommendations on types of alternative revenue sources that may exist for covering the costs of Exchange functions and their appropriateness for future consideration.

2. State Selection of Benchmark Plan (§156.111)

Under existing law and regulations, state mandated benefits existing prior to December 31, 2011 may be considered to be part of essential health benefits (EHB) and states are not required to defray their costs. The costs associated with state benefit mandates established after that date, however, must be defrayed by the states and cannot be included in the percentage of premium attributable to EHB for the purpose of calculating premium tax credits. Exceptions to the defrayal requirement are provided when state laws or regulations are modified to be consistent with federal rules or laws relating to EHB.

In the 2021 Payment Notice, HHS finalized that annual reporting of state-required benefits would begin in plan year 2021 with the first report due July 1, 2021. In this proposed rule, HHS sets July 1, 2022 as the deadline for the second year of reporting. HHS reviews that the reports must identify any benefits in addition to EHB that QHP must cover in plan year 2022 by any state action taken by May 2, 2022. States must also identify state-required benefits that are not in addition to EHB and therefore do not require defrayal. For each subsequent reporting cycle, the state is only required to update the content from the prior report and if there have been no changes to state-required benefits since the previous cycle, the state should affirmatively indicate that to HHS.

HHS proposes May 6, 2022 as the deadline for each state to submit the its EHB-benchmark plan selection for the 2023 plan year. States must also notify HHS by that date if they will permit issuers to substitute benefits between EHB categories.

3. Premium Adjustment Percentage (§156.130)

The premium adjustment percentage 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 2022 is approximately 44.1%.

Using the proposed premium adjustment percentage to calculate the maximum annual limitations on cost-sharing for 2022 results in those amounts rising to $9,100 for self-only coverage and $18,200 for other than self-only coverage. This would represent about a 6.4% increase over the amounts for 2021.

(a) Reduced Maximum Annual Limitation on Cost-sharing (§156.130)

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.[6] Using a process similar to the one used in the 2014 – 2021 Payment Notices, HHS finds that the maximum annual limitation on cost-sharing for people with income between 200% and 250% requires additional adjustment as in prior years. The resulting adjusted maximums proposed for 2022 are identified in Table 9 and are as follows:

Eligibility Category	Reduced Maximum Annual Limitation on Cost-sharing for Self-Only Coverage*	Reduced Maximum Annual Limitation on Cost-sharing for Other than Self-Only Coverage*
Individuals eligible for cost-sharing reduction with income between 100 and 150% of FPL	$3,000	$6,000
Individuals eligible for cost-sharing reduction with income between 150 and 200% of FPL	$3,000	$6,000
Individuals eligible for cost-sharing reduction with income between 200 and 250% of FPL	$7,250	$14,500

* In Table 9 of the published proposed rule, these headers identify the limits as applicable to 2020, which appears to be in error.

(b) Publication of the Premium Adjustment Percentage, Maximum Annual Limitation on Cost Sharing, Reduced Maximum Annual Limitation on Cost Sharing, and Required Contribution Percentage (§156.130)

[6] As specified in statute, the actuarial values of a silver metal level plans must be increased to 73% for individuals with household income between 200 and 250% of the federal poverty level (FPL); to 87% for those with income between 150% and 200% FPL; and to 94% for those with income between 100 and 150% FPL.

Beginning with the 2023 plan year, unless proposing methodological changes, HHS proposes to publish these parameters in guidance by January of the year preceding the applicable benefit year. If a change to the methodology for calculating one or more of the parameters is being proposed, HHS must propose those values and new methodologies in notice-and-comment rulemaking.

The guidance would also include related parameters available at the time of publication. This proposal responds to stakeholders who have requested earlier publication of the parameters to allow for them to be incorporated into rate setting processes and benefits templates earlier.

4. Network Adequacy Standards (§156.230)

HHS adds a clarification that network adequacy standards described in §156.230 do not apply to plans that do not use a provider network or that do not vary benefits based on network participation. HHS states that it has not in the past applied these standards to such plans, but the clarification eliminates any ambiguity.

5. Termination of Coverage or Enrollment for Qualified Individuals (§156.270)

HHS does not propose any changes to existing policy requiring QHPs to send termination notices with effective dates and the reason for termination to enrollees who are terminated with certain exceptions. It inadvertently, however, omitted discussion of two comments when the notices were finalized in the 2021 Payment Notice. The two commenters opposed the proposal raising concerns about unnecessary administrative costs and causing confusion for enrollees who are simply moving from one QHP to another. HHS replies that it continues to believe the notices are necessary noting that one of the largest sources of casework is addressing complaints about termination and increased communication is necessary to address those complaints. In addition, HHS provided for some implementation discretion for issuers using the federal platform to have until February 2021 to implement the requirement.

6. Prescription Drug Distribution and Cost Reporting by QHP Issuers (§156.295)

Existing §156.295 requires QHP issuers to provide certain prescription drug information to HHS but does not specify the responsibility of a PBM to provide such information. As a result, issuers who utilize PBMs often must first obtain the information from their PBM contractors and then submit it to HHS. The information that must be provided includes information on prescriptions, generics, rebates, discounts and other price concessions.

HHS proposes to modify this provision to only require an issuer to report the data if it administers a prescription drug benefit without the use of a pharmacy benefit manager. As explained further below (see new Part 184), HHS also proposes to establish a requirement for PBMs to submit the information directly to HHS.

In addition, HHS proposes two modifications to the information that a QHP issuer must report.

- It would eliminate the requirement for spread pricing amounts since those tend only to be present when there is a PBM administering the drug benefit for the issuer.
- It would remove the requirement that the data are reported by pharmacy types since pharmacy type is not a standard classification in industry database files. HHS states that this would reduce the reporting burden for issuers.

7. Oversight of APTC, CSR, and User Fee Programs (§156.480)

HHS proposes amendments to clarify the oversight and audit authority regarding APTC, CSR, and User Fee Programs. The amendments would consolidate regulations and establish additional details for those audits, include the authority to oversee user fee programs in addition to APTC and cost-sharing reductions, and to establish that where a state fails to substantially enforce the standards, HHS would do so.

HHS proposes to rename §156.480 to include the "user fee program" in the title and establish that it or its designee may audit or conduct a compliance review of an issuer of a risk adjustment covered plan following the standards in §156.715 (a section describing compliance reviews for QHP issuers in federally-facilitated Exchanges). In addition:

- HHS would be required to provide at least 15 calendar days advance notice of intent to conduct an audit.
- Audits would have an entrance conference at which the scope of the audit would be presented and an exit conference at which the initial audit findings would be discussed.

Issuers would be required to:

- Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with an audit or compliance review;
- Submit complete and accurate data to HHS in the form and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established at the entrance conference;
- Respond to all requests for supplemental information no later than 15 calendar days after the date of the request.
- In circumstances in which an issuer cannot provide the requested data within the applicable timeframe, it can request an extension. The request must be submitted within the applicable timeframe and detail the reason for the extension request and the good cause in support of the request. If granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension.
- An issuer would have 30 calendar days to respond to HHS' preliminary findings and if it does not dispute or respond to those findings, they become final. If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.
- The issuer must:
    - Comply with the actions set forth in the final audit report,

- Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval and implement that plan,
- Provide documentation of the corrective actions once taken.

If an issuer fails to comply with the audit activities specified by HHS, it will notify the issuer of payments that the issuer has not adequately substantiated and that it may recoup them. [7]

8. Subpart I- Enforcement Remedies in Federally-Facilitated Exchanges (§156.800)

CMS proposes to rename Subpart I to "Enforcement Remedies in the Exchanges" instead of "in Federally-Facilitated Exchanges" to make clear that the enforcement remedies available may also apply in state Exchanges or SBE-FP Exchanges in particular when states have failed to enforce federal requirements. Consistent with that change, HHS would amend paragraph §156.800(b) which describes the plans to which such remedies could apply to add that they may also apply for non-compliance by QHP issuers participating in state Exchanges or SBE-FP Exchanges where HHS is responsible for enforcement.

HHS solicits comment on how HHS can collaborate with Exchanges to proactively address non-compliance and to share compliance tools regarding CSRs, APTC and user fees.

9. Imposing Civil Money Penalties (CMPs) (§156.805)

Consistent with the provision above, in this section HHS proposes to change references to "Federally-Facilitated Exchanges" to "Exchanges" including in the title of the section to be clearer that HHS may impose CMPs on QHP issuers in states where HHS is responsible for enforcement. In addition, it proposes to specify that HHS will enforce the requirements of Subpart E (Issuer responsibilities with respect to APTCs and CSRs) if a state Exchange or SBE-FP notifies HHS that it is not enforcing the requirements or if HHS makes a determination that the state Exchange or SBE-FP is failing to enforce the requirements. It also permits HHS to impose CMPs on an issuer for violation of issuer responsibilities under Subpart E.

10. Subpart J – Administrative Review of QHP Issuer Sanctions (§§156.901, 156.927, 156.931, 156.947)

HHS proposes to eliminate from the title of Subpart J "in Federally Facilitated Exchanges" so that it becomes "Administrative Review of QHP Issuer Sanctions" consistent with earlier provisions to clarify that the sanctions could apply to any QHP regardless of the type of Exchange they participate in.

In addition, HHS proposes several other changes to align these administrative review rules with the Departmental Appeals Board's current practices for administrative hearings to appeal CMPs:

[7] The regulatory text here refers to risk adjustment payments which is likely in error since this section addresses APTC, CSRs and user fees rather than risk adjustment payments.

- To remove requirements to file submissions in triplicate and instead require electronic filing,
- To allow video conferencing as a form of administrative hearing, and
- To permit the Administrative Law Judge to communicate the next steps for a hearing in either the acknowledgement of a request for hearing or on a later date.

11. Quality Rating System (QRS) (§156.1120) and Enrollee Satisfaction Survey System (§156.1125)

HHS continues to receive feedback from stakeholders about the QRS and the QHP Enrollee Survey and is considering additional refinements to each. It has received many comments recommending that it remove levels of the QRS hierarchy to help streamline and improve consumers' understanding of quality rating information. HHS explains that the hierarchy establishes the organization for scoring, rating and reporting of measures. It consists of composites, domains, and summary indicators. It recognizes that a simplified QRS hierarchy can improve alignment with other CMS quality reporting programs. As such, it seeks comment on which level or levels of the QRS hierarchy should be removed.

In addition, HHS proposes to make the full QHP Enrollee Survey results publicly available in an annual Public Use File beginning with the 2021 QHP Enrollee Survey results. Presently, it makes only some of the enrollee experience results available via posting on HealthCare.gov. The data posted would include the score and proportion of responses for every survey question and composite as well as demographic information such as employment status, race, and ethnicity, and age at the reporting unit and national level.

12. Dispute of HHS Payment and Collections Reports (§156.1210)

Under existing rules, issuers are required to respond to payment and collections reports from HHS by identifying any inaccuracies in enrollment or payment data in the report. Issuers have 90 days to do so. That timeline had been only 15 days but was extended to 90 days in the 2021 Payment Notice. HHS has learned that there are some data inaccuracies that may not reasonably be known in a 90-day timeframe. For example, an appeal of Exchange eligibility may not be completely adjudicated within 90 days.

To address such inaccuracies, HHS proposes to add new paragraph (b) to address those inaccuracies identified after 90 days. Under the proposal, HHS would consider and work with the issuer to resolve the inaccuracy as long as the issuer notifies HHS within 15 calendar days after identifying the inaccuracy and the failure to identify the inaccuracy in a timely manner was not unreasonable or due to misconduct or negligence. HHS adds in new paragraph (c) that such inaccuracies may be reported up to 3 years following the end of the plan year. If an inaccuracy is discovered after the 3-year period, the issuer must notify HHS and repay any overpayment.

HHS seeks comment on the impact of this proposal on state Exchanges' ability to resolve disputes and report payment adjustments to HHS.

13. Payment and Collection Processes (§156.1215)

Consistent with the proposal described above, HHS proposes to amend this provision to eliminate the flexibility for HHS to collect some or all of a state's user fee on their behalf.

14. Administrative Appeals (§156.1220)

HHS proposes conforming amendments to conform the appeals provisions here with the clarification proposed and described above to make clear that issuers may appeal the calculation of risk adjustment second validation audits only "if applicable." The right to appeal is only applicable when issuers have insufficient pairwise agreement between first and second validation audits. In addition, it would clarify that the 30-day timeline for an issuer to file a request for reconsideration of a second validation audit finding is 30 calendar days from the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Transfers.

15. Enrollment Process for Qualified Individuals (§156.1240)

Under §156.1240(a)(1), QHP issuers are required to accept payments for enrollment that at a minimum include paper checks, cashier's checks, money orders, debit cards, etc. HHS proposes to add new (a)(3) requiring issuers to accept payments on behalf of an enrollee from an individual coverage Health Reimbursement Account or a qualified small employer health reimbursement arrangement (QSEHRA.)

F. Part 158 – Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Definitions (§158.103)

HHS proposes a new definition for the term "Prescription drug rebates and other price concessions": All direct and indirect remuneration received or receivable by an issuer and entities providing pharmacy benefit management services to the issuer, related to the provision of a prescription drug covered by the issuer, regardless from whom the remuneration is received (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, vendor). Direct and indirect remuneration includes discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers, and excluding bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

The definition is needed since amendments to the MLR were finalized (85 FR 29164) that require issuers to deduct from incurred claims all prescription drug rebates as well as price concessions received and retained by a PBM for MLR reporting purposes. HHS notes that the proposed definition is consistent with the definition used for required reporting of rebates, discounts, and price concessions under section 1150A of the Social Security Act and as described in §156.295 (which applies the SSA reporting requirements to issuers) and excludes bona fide service fees.

2. Premium Revenue (§158.130)

In response to the COVID-19 PHE, HHS instituted a temporary policy permitting issuers in the small group and individual markets for insurance to offer temporary premium credits for 2020. In this proposed rule, HHS clarifies and proposes that for the 2021 MLR reporting year and beyond, that such temporary credits should be counted as reductions to earned premium for the purpose of MLR reporting.

3. Rebating Premium if the Applicable Medical Loss Ratio Standard is Not Met (§158.240)

Another policy implemented in response to the COVID-19 PHE, was to permit issuers to prepay to enrollees a portion or all of their estimated MLR rebates for the 2019 reporting year. HHS proposes to codify and make permanent the ability of issuers to prepay some or all of the estimated MLR rebates for an MLR reporting year. Under proposed §158.240(g), issuers choosing to prepay MLR rebates would be required to:

- Make pre-payments for all eligible enrollees in a given state and market in a non-discriminatory manner;
- If, after determining the total rebate owed for the MLR reporting year, the prepayment was 95 percent of that amount, the issuer could rebate the remaining 5 percent or less in the following year's MLR rebate payment without being penalized. The remaining amount cannot be treated as a de minimis amount, however. (Under existing rules, if a total rebate for an MLR year is below the de minimis threshold, an issuer does not need to make a rebate payment.)

HHS states that it intends to revise the MLR reporting form instructions to describe how such prepayments must be reported and to clarify how an issuer can recoup prepaid amounts that the issuer subsequently determines were more than were owed.

4. Form of Rebate (§158.241)

MLR rebates may be paid in the form of a premium credit, lump-sum check or lump sum if premiums were paid via credit or debit card. HHS proposes to amend paragraph §158.241(a)(2) to state that when rebates are provided in the form of a premium credit, they must be applied to the premium due no later than October 30th following the MLR reporting year. This provision would be applicable beginning with the 2020 MLR reporting year (MLR reports due in 2021.)

G. Part 184 – Prescription Drug Distribution and Cost Reporting by Pharmacy Benefit Managers (§§184.10 and 184.50)

As touched on above with respect to QHP issuer reporting of prescription drug information, HHS is proposing to establish new Part 184 to codify the requirements that PBMs under contract with QHP issuers must report the data required under section 1150A(b) of the SSA as established in the Affordable Care Act.

The proposed amendments would require in a form, manner, and at the times specified by HHS, a PBM providing services to a QHP to provide to HHS:

- The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;
- The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the PBM negotiates under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed; and
- The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

Consistent with QHP reporting, HHS would not be permitted to disclose information collected under this section unless it is de-identified or it is for certain specific purposes identified in the statute including to allow the Comptroller General or the Congressional Budget Office to use the information, or to allow states to carry out their Exchange administration duties.

HHS would have the authority to apply penalties to a PBM that fails to report the required information to HHS on a timely basis or knowingly provides false information. Penalties applicable to drug manufacturers who fail to report required information for calculating Medicaid drug rebates would apply to PBMs under this proposal.

IV. State Innovation Waivers

HHS and the Department of the Treasury propose to incorporate by reference in several places in existing regulations, guidance published in October of 2018 relating to the granting of waivers under section 1332 of the Affordable Care Act (State Relief and Empowerment Waivers, 83 *FR* 53575).

The Departments state that by codifying the guidance, states will have more consistency and predictability and will better understand how a proposal can receive approval and how they can remain in compliance. The Departments describe the features of the 2018 guidance including the guardrails that must be met for approval -- (1) The proposal must provide coverage that is at least as comprehensive as coverage defined in PPACA section 1302(b) and offered through Exchanges; (2) the proposal must provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable for the state's residents as would

be provided under title I of PPACA; (3) the proposal must provide coverage to at least a comparable number of the state's residents as would be provided under title I of PPACA; and (4) the proposal must not increase the federal deficit. They further describe application review procedures, analytic requirements and operational considerations included in the guidance.

Existing HHS and Treasury rules in 31 CFR 33.108 and 45 CFR 155.1308 describe application procedures for states seeking waivers under section 1332 including public notice requirements, enactment of state legislation, and an implementation plan. The Departments propose to add that states must supply the analyses, actuarial certifications, data, assumptions, targets and other information to the Secretaries to satisfy the general requirements for approval consistent with the 2018 guidance. They state that the October 2018 Guidance includes additional application review procedures, information for calculating pass-through funding, and certain analytical requirements and operational considerations.

Existing HHS and Treasury rules in 31 CFR 33.120 and 45 CFR 155.1320 describe monitoring and compliance requirements. The rules give the Secretaries the right to terminate a waiver if they determine that a state has failed to comply with the terms and conditions of the waiver and describe the process for addressing complaints. The Departments propose to add to the existing compliance requirements that states must also comply with the October 2018 guidance.

Existing HHS and Treasury rules in 31 CFR 33.128 and 45 CFR 155.1328 describe a requirement for the Secretaries to periodically evaluate programs operating under section 1332 waivers. They propose to establish that periodic evaluations must be consistent with the October 2018 Guidance.

V. Collection of Information Requirements

HHS identifies two provisions in the proposed rule for which it estimates potential burden and that would require an information collection review and approval under the Paperwork Reduction Act of 1995.

- Direct enrollment issuers and web-sites will be required to submit certain operational data, a web-broker agreement, and to demonstrate operational readiness and to submit to a security and privacy audit. HHS estimates that these activities together will cost a total of $250,000 and would impact between 4 and 77 entities.
- Requirements for prescription drug data reporting by QHP issuers and PBMs that contract with those issuers would result in costs for approximately 40 PBMs that contract with all of the approximately 275 issuers. They would face costs of about $2.7 million per year for data submission (about $66,719 per PBM) and an average annual burden of $6.5 million for 2021 through 2023 for the technical build (or about $356,128 per PBM per year.) QHPs would also face a small additional burden totaling $72,534 to coordinate with PBMs to identify QHP plans.

VI. Regulatory Impact Analysis (RIA)

OMB has determined that this proposed rule is "economically significant" within the meaning 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 discusses the proposed rule's estimated costs and benefits. Comments are invited on the estimates and qualitative impacts included in the RIA.

Table 12 of the proposed rule summarizes HHS' assessment of the qualitative and quantitative impacts and estimated direct monetary costs and transfers that would result from the proposals.

HHS does not expect the proposed rule to change the budget effect of the premium stabilization programs, which are summarized in Table 13 of the proposed rule. That table presents the Congressional Budget Office estimates from May 2020, showing collections and payments for the premium stabilization programs each totaling $34 billion for the period 2022-2026. HHS says that its own analyses conclude that the proposed rule effects are consistent with the estimates it provided in the 2021 Payment Notice with respect to the APTCs, the premium stabilization programs, and FFE user fee requirements.

It estimates that the costs to issuers audited under the risk adjustment program and with reinsurance program audits will each cost between $430,692 and $861,384 but its proposal to permit states to make multi-year requests for a reduction in risk adjustment transfers will reduce burden. If 5 states take advantage of the flexibility, HHS estimates it would reduce costs by a total of $21,806.

HHS discusses the estimated savings to Exchanges from the proposal to eliminate the requirement for random sampling to verify enrollment in or eligibility for employer-based insurance when the Exchange reasonably expects that it will not obtain sufficient verification data. It estimates a total one-time savings of $113 million for 15 state Exchanges and Exchanges using the federal platform by relieving exchanges of the requirement to conduct sampling for benefit year 2022.

Other quantitative estimates provided include:

- The costs of requiring the 4 states that do not now implement pre- or post-enrollment SEP verification will be about $48 million plus $60 million for 5 states planning to move to state Exchanges after 2021.
- Reduced user fees are estimated to result in lower transfers from issuers to the federal government of about $270 million.
- Additional specification around audits relating to APTCs, CSRs and user fees is estimated to raise the costs of compliance for each of 30 to 60 issuers by about $14,236 each for a total cost of between $430,692 and $861,384.

A discussion of the non-quantified benefits and costs of other proposals are reviewed and are summarized in Table 12.