Affordable Care Act: Notice of Benefit and Payment Parameters for 2021 (CMS-9916-P); Summary of Proposed Rule

February 4, 2020

On January 31, 2020, the Centers for Medicare & Medicaid Services (CMS) of the Department of Health and Human Services (HHS) made available for public display its proposed Notice of Benefit and Payment Parameters for 2021 (Payment Notice).[1] The Payment Notice proposes policy changes including those related to the risk adjustment and risk adjustment data validation programs, automatic re-enrollment practices and special enrollment periods. It would require annual state reporting of state-required benefits and describes a new Value Based Insurance Design plan. In addition HHS requests feedback on a set of questions relating to coverage provided to an individual while a coverage appeal is pending.

Comments are due on March 2, 2020. The proposed rule is scheduled to be published in the Federal Register on February 6, 2020. It is accompanied by release of the draft Letter to Issuers in the FFEs[2] and Key Dates for Calendar Year 2020.[3]

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[1] Available at https://www.federalregister.gov/documents/2020/02/06/2020-02021/benefit-and-payment-parameters-notice-requirement-for-non-federal-governmental-plans.
[2] Available at https://www.cms.gov/files/document/2021-draft-letter-issuers-clearance-version-final-13120.pdf,
[3] Available at https://www.cms.gov/files/document/proposed-key-dates-tables-cy2020.pdf.

I. Summary of Major Provisions

Risk Adjustment Program. In addition to regular updates to its risk adjustment model, HHS proposes a set of updates to Hierarchical Condition Categories (HCCs) including those resulting from transitioning to the use of the ICD-10. It requests feedback on a set of potential prediction model improvements for future years to address under-prediction of risk for low-cost enrollees and over-prediction of risk for high-cost enrollees.

Automatic Re-enrollment and Redeterminations. HHS proposes several changes to re-enrollment and redetermination requirements. It proposes to change automatic re-enrollment rules so that individuals in plans with advance premium tax credits (APTCs) that cover their full premium would be automatically re-enrolled in a lower APTC plan. In addition, it would eliminate the need for redeterminations under certain circumstances when an enrollee has provided permission to have their coverage terminated and periodic checking indicates dual enrollment or that the enrollee is deceased.

Special Enrollment Periods. HHS proposes several new flexibilities for enrollment rules for individuals enrolling through special enrollment periods, including allowing for those newly ineligible for cost sharing reductions (CSRs) to enroll in a plan other than a silver-metal level plan and would permit special enrollment to apply to parents who become newly eligible and who have dependents who are already enrolled in qualified health plans (QHPs).

Use of Copay Accumulators. HHS proposes to permit issuers and group health plans to determine whether to include or exclude the value of manufacturer copay cards, discounts or other direct support from manufacturers from the annual limitation on cost sharing regardless of whether or not a generic is available.

Eligibility Pending Appeals. HHS requests feedback on a set of questions relating to coverage provided to an individual while a coverage appeal is pending (eligibility pending appeals). Questions relate to whether coverage options should be expanded, if requests for eligibility pending appeal should be subject to a time limit, how life changes that occur during an appeal should be taken into account, how issuers should retroactively apply changes to a person's coverage after the appeal has been finalized, and how non-payment grace periods should apply to eligibility pending appeals.

Annual Reporting of State-Required Benefits. HHS proposes new annual state reporting of state-required benefits that are in addition to essential health benefits (EHBs) for the purpose of making sure states are deferring the costs of those benefits consistent with statute.

Promoting Value Based Insurance Design. HHS proposes a new value-based design QHP that would encourage the use of high value services. It identifies a set of high-value and low-value services for which such plans would modify cost-sharing requirements in order to encourage greater use of high-value services and less use of low-value services.

Summary of Final 2020 and Proposed 2021 Parameters: Selected Provisions		
Provision	**Final 2020 Plan Year**	**Proposed 2021 Plan Year**
Required contribution percentage for exemption from mandate	8.24%	8.27%
Annual enrollee out-of- pocket cost-sharing maximum	$8,150/$16,300*	$8,550/$17,100*
Reduced out-of-pocket cost-sharing maximums at specified percentages of the federal poverty level (FPL)		
• 200-250% of FPL	$6,500/$13,000*	$6,800/$13,600*
• 150-200% of FPL	$2,700/$5,400*	$2,850/$5,700*
• 100-150% of FPL	$2,700/$5,400*	$2,850/$5,700*
Risk adjustment program annual user fee (per billable enrollee)	$2.16	$2.28
Federally Facilitated Exchange user fee	3.0% of premium	3.0% of premium
State-based Exchange with Federal Platform (SBE-FP) user fee	2.5% of monthly premium	2.5% of monthly premium
* Amounts for out-of-pocket limits and deductibles presented as "single policy/family policy."		

II. Background

A. Legislative and Regulatory Overview

HHS reviews the statutory and regulatory history related to the implementation of the Exchanges and related topics. HHS states that the proposed rule aims to ensure taxpayer money is more appropriately spent and that states have flexibility and control over their insurance markets. Benefits would be reduced regulatory burden, reduced administrative costs for issuers and states, and lower net premiums for consumers resulting in increased access to affordable health coverage.

B. Stakeholder Input

HHS sought advice from stakeholders on policies related to the operation of Exchanges and the premium stabilization programs, and considered this input in developing the policies in this proposed rule. It solicited input from states on topics including EHB, state mandates, and risk adjustment. 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 2021

A. Part 146 – Requirements for the Group Health Insurance Market: Excepted Benefit HRAs Offered by Non-Federal Governmental Plan Sponsors

In 2019, HHS in concert with the Department of Labor and the Department of Treasury authorized two new types of Health Reimbursement Arrangements (HRAs) -- individual coverage HRAs and limited excepted benefits HRAs. Individual coverage HRAs can be used to reimburse medical care expenses and premiums for individual health insurance coverage. Limited excepted benefits HRAs are considered to be excepted benefits plans (not subject to requirements under title XXVII of the Public Health Service Act) if they: (1) are offered by a plan sponsor that also offers traditional group health plan coverage for the plan year to the participant; (2) are funded with amounts that do not exceed $1,800 adjusted annually for each plan year; (3) do not reimburse premiums for individual health insurance coverage, group health plan coverage, or Medicare, and (4) are made available under the same terms to all similarly situated individuals, regardless of any health factors.

HHS proposes to add a notice requirement that non-Federal government sponsors of excepted benefit HRAs must provide to participants of the HRAs informing those individuals about the conditions for eligibility for benefits and annual or lifetime limits, and describing the benefits available. Notices must be provided annually with the first occurring no later than 90 days after the employee becomes a participant.

The notice provision would become effective for plan years beginning on or after 30 days following the effective date of the final rule.

HHS solicits comment on the proposed timelines for the notice as well as the start date for the notice requirement. HHS specifically seeks comment on whether, after the first notice is issued, notices should only be required for later plan years if there is a change in the terms of the excepted benefit HRA, and if so, the type or magnitude of changes that should trigger such notices.

B. Part 149 – Requirements for the Early Retiree Reinsurance Program (ERRP)

HHS proposes to delete Part 149 of title 45 which sets forth the requirements for the ERRP since that program sunsetted January 1, 2014 and there are no outstanding claims or disputes remaining.

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

1. Sequestration

Both the transitional reinsurance program and permanent risk adjustment program are subject to fiscal year (FY) 2020 sequestration.[4] Although the 2016 benefit year was the final year of the

[4] See the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year (FY) 2020, Available at https://www.whitehouse.gov/wp-content/uploads/2019/03/2020_JC_Sequestration_Report_3-18-19.pdf.

transitional reinsurance program, there may be reinsurance payments that may be made in FY 2021 as the program closes out. The reinsurance and risk adjustment programs will each be sequestered at a rate of 5.9 percent for payments made from funds collected during FY 2020. Funds sequestered in FY 2020 from the reinsurance and risk adjustment programs will become available for payment to issuers in FY 2021 without further congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, these programs will continue to be sequestered in future fiscal years; any sequestered funding would become available in the fiscal year following that in which it was sequestered.

2. Provisions and Parameters of the Risk Adjustment Program

Standards for administration of the risk adjustment program created by the Affordable Care Act (ACA) are set out in subparts 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 2021 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 beginning for the 2017 benefit year, and prescription drug utilization factors (RXCs) beginning for the 2018 benefit year. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children or infants is multiplied by a 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.

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

HHS proposes changes to recalibrate risk adjustment models consistent with the methodology used for the 2020 benefit year and continuing the transition to the use of only enrollee-level EDGE data rather than a combination of EDGE and MarketScan data.[5] For 2021, it proposes to incorporate the most recent benefit year of enrollee-level EDGE data and to rely only on

[5]HHS is transitioning 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.

EDGE data for 2021 and thereafter, discontinuing any use of the MarketScan® data for recalibration. HHS proposes to use 2016, 2017 and 2018 enrollee-level EDGE data.

Because of the timing of the proposed rule, HHS does not have 2018 data for the estimated coefficients displayed in Tables 2-7 of the proposed Payment Notice but believes that using the 2016 and 2017 data has provided reasonably close approximations. HHS notes that if it is unable to incorporate the 2018 benefit year data in time to publish updated coefficients in the final rule, it will publish the final coefficients in guidance after the publication of the final rule consistent with the approach it has used in previous benefits years.

(ii) Updates to the Risk Adjustment Model Recalibration Hierarchical Condition Categories (§153.320)

HHS reviews its examination of potential updates addressed in its June 17, 2019 HHS-HCCs Update Paper[6] including incorporating coding changes made in the transition to the ICD-10 diagnosis classification system. HHS also reviews its considerations for examining potential changes, and its principles for guiding the HHS-HCC diagnostic classification system, initially described in the proposed Payment Notice for 2014.[7]

HHS conducted a comprehensive review of the current HHS-HCC classification and risk adjustment model classification. It examined disease groups with extensive ICD-10 code classification changes, HCCs with big count changes following ICD-10 implementation, clinical areas of interest (for example, substance use disorder), and modelled under- and over-prediction. HHS tested different configurations and multiple model variations and took into account the predictive power, complexity, and coding incentives inherent in any potential reclassifications. The following table (Table 1 from the proposed Payment Notice) summarizes the proposed model changes for 2021 which have been incorporated in the estimated coefficients displayed in Tables 2-7 of the proposed Payment Notice.

[6] "Potential Updates to HHS-HCCs for the HHS-operated Risk Adjustment Program" (June 17, 2019), https://www.cms.gov/CCIIO/Resources/Regulations -and-Guidance/Downloads/Potential-Updates-to- HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf .

[7] See the HHS Notice of Benefit and Payment Parameters for 2014, Proposed Rule, 77 FR 73118 at 73128 (December 7, 2012).

TABLE 1: Summary of Proposed Payment HCC Risk Adjustment Model Changes

Condition	Payment HCC Proposed Change	Summary of Proposed Payment HCC Changes
Payment HCC Changes		
Substance Use Disorders	+3	• Add 2 new HCCs for alcohol use disorders and one new HCC for lower severity drug use disorders to risk adjust for a larger number of substance use diagnoses for all models.[1] • Reconfigure drug dependence HCC to include drug use disorders with non-psychotic complications and a subset of drug poisoning (overdose) codes to reflect the revised conceptualization of substance use disorders in ICD-10 for all models. • Impose a new combined hierarchy on drug use and alcohol use HCCs due to the high prevalence of both drugs and alcohol use among those with alcohol or drug use disorders for all models.
Pregnancy	+3	• Add 3 (ongoing) pregnancy-without-delivery HCCs, leaving them ungrouped in the adult models (to reflect differences in costs by level of complications) and grouping them in the child models (to address small sample sizes and unstable estimates). • Revise two existing pregnancy HCC Groups in both adult and child models, separating out the ectopic/molar pregnancy HCC and the uncomplicated pregnancy-with-delivery HCC to better distinguish incremental costs.
Diabetes: Type 1	+1	• Add a diabetes type 1 additive HCC to the adult models to distinguish additional costs for diabetes type 1. • Remap hyperglycemia and hypoglycemia codes in the adult model from the "chronic complications" HCC to the "without complication" HCC based on clinical input.
Asthma	+1	• Split current asthma HCC into two severity-specific HCCs given new clinical distinctions for severity levels in the ICD-10 and to distinguish costs by severity for all models. • Continue to group asthma HCCs with chronic obstructive pulmonary disease HCC in adult model and leave the 3 HCCs ungrouped to • distinguish costs in child models.
Fractures	-1 +1	• Delete an HCC (pathological fractures) to address a clinical distinction that may be inconsistently diagnosed/coded for all models. • Reconfigure an existing HCC (hip fractures) to better distinguish fracture codes by site for all models. • Add a new HCC (vertebral fractures) to better predict vertebral fractures, which may be indicative of chronic disease and frailty for all models.
Third Degree Burns and Major Skin Conditions	+2	• Reconfigure and add 2 HCCs (extensive third-degree burns; major skin burns or conditions) in an imposed hierarchy because these HCCs are currently being under-predicted, contain chronic conditions or are burns that involve long-term follow up care for all models. • Impose an *a priori* constraint[2] between extensive third degree burns and severe head injury in child models due to small sample size.

Condition	Payment HCC Proposed Change	Summary of Proposed Payment HCC Changes
Coma and Severe Head Injury	+1	• Add a new severe head injury HCC (represents a condition with ongoing care costs; similar to the inclusion of other injury HCCs) in a hierarchy above the coma/brain compression for all models. • Impose an *a priori* constraint between extensive third degree burns and severe head injury in the child models due to small sample size.
Traumatic Amputations	+1	• Add a new HCC in a hierarchy with the current amputation status HCC and reconfigure codes between the new HCC and current amputation status HCC to better distinguish early treatment and complication costs from long-term costs for all models. • Leave HCCs ungrouped in the adult models; group them in the child model for coefficient stability purposes due to small sample size.
Narcolepsy and Cataplexy	+1	• Add a new HCC to both child and adult models because these conditions are currently under-predicted and have associated treatment costs.
Exudative Macular Degeneration	+1	• Add a new HCC to adult models because the condition is currently • under-predicted; costs are primarily related to drug treatments.
Congenital Heart Anomalies	new to adult	• Add 3 new HCCs to adult models (already in the child and infant models) because the conditions are currently under-predicted. Group them in the adult models only.
Changes in HCC Groups, Hierarchies		
Metabolic and Endocrine Disorders	N/A	• Group HCCs 26 and 27 together in both the child and adult models to distinguish their significantly higher incremental costs from other HCCs (HCCs 28-30) previously in the full group (HCCs 26 and 27 are currently under-predicted in the models due to grouping). • Ungroup HCCs 29 and 30 in the adult models as they have adequate sample sizes and clinical and cost distinctions. • Group HCCs 28 and 29 in the child models due to small sample sizes, clinical similarity, and similar predicted costs. • Leave HCC 30 ungrouped in the child models because it is clinically distinct from HCCs 28 and 29.
Necrotizing Fasciitis	N/A	• Ungroup the necrotizing fasciitis HCC (HCC 54) in the adult models to better predict higher incremental costs compared to HCC 55 (the condition that is currently grouped with this HCC).
Blood Disorders	N/A	• Revise groups in both adult and child models to move HCC 69 from its previous grouping with HCCs 70 and 71 to the group with HCCs 67 and 68 to better reflect clinical severity and associated costs. • Reconfigure HCCs 69 and 71 in both adult and child models based on clinical input.
Mental Health	N/A	• Move delusional disorders/psychosis HCC above major depressive disorders/bipolar disorders HCC in the hierarchy and renumber the HCCs (that is, HCCs 88 and 89 switch positions) because the costs and diagnoses associated with the HCC are more aligned with HCC 87 (Schizophrenia) for all models. • Relabel HCCs to align with ICD-10 categorizations for all models.
Cerebral Palsy and Spina Bifida	N/A	• Refine hierarchies to exclude paralysis HCCs for enrollees with cerebral palsy HCCs, as ICD-10 coding guidelines prohibit these conditions from coding together for all models. • Refine hierarchies to exclude hydrocephalus HCC for enrollees with spina bifida HCC for similar coding restriction purposes for all models.

Condition	Payment HCC Proposed Change	Summary of Proposed Payment HCC Changes
Pancreatitis	N/A	• Reconfigure the acute pancreatitis HCC to move pancreatic disorders and intestinal malabsorption out of the acute pancreatitis HCC to differentiate higher cost conditions for all models. • Revise the hierarchy for pancreas transplant HCC to remove exclusion of pancreatitis HCCs because pancreas transplants are done primarily for diabetes and insulin conditions rather than pancreatitis for all models.
Liver	N/A	• Reconfigure codes in liver HCCs to reflect clinical distinctions for all models. • Move acute liver failure HCC above chronic liver failure HCC in the hierarchy and renumber HCCs to address cost implications of chronic versus acute liver failure for all models.
Summary of the Adult Model Specific Changes		
Payment HCC change	+17	• Net change of 17 HCCs; 18 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Severe Illness Interactions	-1 (other model variable)	• Remove medium cost severe illness interaction term from model because its parameter estimate is usually very low or negative.
Summary of the Child Model Specific Changes		
Payment HCC change	+12	• Net change of 12 HCCs; 13 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Transplant *A Priori* Constraints	N/A	• Revise *a priori* constraints applied to the transplant HCCs to better distinguish costs while improving estimate stability due to small sample sizes, and remove a constraint on HCC 129 Cystic Fibrosis based on HCC 158 Lung Transplant Status/Complications due to the high associated drug costs and higher predicted costs.
Summary of the Infant Model Specific Changes		
Payment HCC change	+8	• Net change of 8; 9 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Categorical Model	N/A	• Revise severity level assignments of a subset of HCCs to better reflect clinical severity and costs and assign new HCCs to severity levels. • Reconfigure code assignments to newborn HCCs for subset of codes whose weeks gestation classification in ICD-10 differed from ICD-9.

Notes:
[1] "All models" refers to the adult, child and infant models.
[2] In *a priori* constraints, the HCC estimates are constrained to be equal to each other. These are applied to stabilize high cost estimates that may vary greatly due to small sample size.

HHS points out that proposed changes to "Transplant *A Priori* Constraints" goes further than described in the HHS-HCC updates paper. This modification is to the constraints that have been placed on HCC 129 Cystic Fibrosis because of small sample sizes. Those constraints result in the higher cost HCC 159 Cystic Fibrosis being constrained to the lower cost 158 Lung Transplant Status/Complications coefficients. HHS proposes to remove that constraint to permit HCC 159 to have higher predicted costs and better reflect the actual hierarchy of costs for the two conditions.

All of the proposed changes in Table 1 would be applied at one time for the 2021 benefit year. HHS provides a crosswalk of ICD-10 codes to the proposed HCCs at

https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html.32 entitled "Draft ICD-10 Crosswalk for Potential Updates to the HHS-HCC Risk Adjustment Model for the 2021 Benefit Year."

In 2020, HHS made a pricing adjustment for one RXC coefficient for Hepatitis C drugs and stated that it would reassess the need for this adjustment for future years. For 2021, HHS proposes to maintain the adjustment constraining the Hepatitis C coefficient to the average expected costs of Hepatitis C drugs.

HHS also proposes including pre-exposure prophylaxis (PrEP) as a preventive service along with general updates to preventive services in the simulation of plan liability for the HHS risk adjustment models in the final 2021 benefit year adult and child models. HHS states that this is in light of the recent recommendation by the U.S. Preventive Service Task Force to expand the use of PrEP as a preventive service that must be covered by applicable health plans for persons who are at high risk of HIV.

HHS also considered adding an additional age-sex category for enrollees age 65 and over. It does not propose to do so at this time but plans to continue to monitor expenditures for older enrollees to determine if additional age-sex coefficients are warranted.

(iii) Improving Risk Adjustment Model Predictions

HHS is considering several improvements to the model to address concerns introduced in earlier Payment Notices that the model under-predicts risk for low-cost enrollees, particularly for those without HCCs, and over-predicts risk for high-cost enrollees, particularly for those with the highest HCC counts. HHS does not propose incorporating any of these changes for the 2021 plan year but seeks comment on the following approaches that it has considered:

- Incorporating a two-step estimation process in which the adult risk adjustment model would be estimated only based on age-sex variables and then re-estimated using the full set of HCCs while constraining the value of the age-sex coefficients to the first estimation. HHS thought this approach would help predict the healthiest sub-populations more accurately but instead found that individual HCCs were under-predicted using this approach – particularly for the most expensive enrollees.
- Making adjustments to plan liability outside of the models for the subpopulations subject to under- and over- prediction. The adjustments would be based on predictive ratios for all five metal levels and within each metal level. Using most recently available EDGE data, however, HHS found that this approach did not improve the predictive ratios relative to the current approach and worsened predictions along other dimensions – particularly for those with no HCCs and those with 1 or more payment HCCs.
- Adding a non-linear prediction term to the formula to reflect the overall disease burden for enrollees with combinations of conditions. The term would be a weighted count of HCCs. This approach may not improve the prediction for all sub-populations, however.
- Adding a condition count similar to the count of HCCs recently added to the Medicare Advantage risk adjustment model. HHS would add eight indicator variables

corresponding to 1 to 8-or-more payment HCCs. HHS points out that like the non-linear prediction term, this approach, however, may not improve prediction for all subpopulations.

HHS notes that both the non-linear prediction term and the condition count approaches do yield gains in the predictive accuracy in the adult silver models. Enrollees with the lowest counts have better predictive ratios under both approaches. HHS does not propose incorporating either approach at this time believing that further evaluation is needed and **seeks comment on what considerations should be taken into account in potentially incorporating such changes and in particular how these models might impact coding incentives.**

HHS is also considering future adjustments to enrollment duration factors in the adult models and is assessing whether those factors should be incorporated into the child and infant models. The adjustments would address the fact that partial year enrollees appear to be more expensive on average than full-year enrollees. HHS believes that eliminating enrollment duration factors and replacing them with monthly enrollment duration factors (up to 6-months) would most improve model prediction for the adult model. In testing those factors, HHS found that they did not improve prediction for the child or infant models. HHS also notes that such changes for the adult model may not be needed once prediction is improved via the addition of the condition count or non-linear term as described above so more work will need to be done.

(iv) List of Risk Adjustment Program Factors

Tables 2 – 7 the Proposed Payment Notice list the proposed Risk Adjustment factors incorporating two years (2016 and 2017) of EDGE data, as well as the HCC changes proposed and described in Table 1 of the Proposed Payment Notice (and duplicated above.)

(v) Cost-sharing Reduction Adjustments

Also consistent with prior years, cost-sharing reductions are incorporated into the risk adjustment models to account for increased plan liability due to higher utilization of health care services by individuals receiving cost-sharing reductions. HHS finalizes as proposed, those amounts in Table 8. For Massachusetts, HHS will continue to use a cost-sharing reduction factor of 1.12 for all Massachusetts wrap-around plans.

(vi) 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 R-squared statistic for each model and benefit year separately in Table 9. If the proposed 2021 benefit year model recalibration data is finalized, HHS will publish updated R-squared statistics to reflect the 2016, 2017, and 2018 datasets for the 2021 plan year.

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

HHS reviews its approach to risk adjustment. It plans to continue the payment transfer formula finalized in the 2020 payment notice and re-publishes the formula in its entirety. The payment transfer formula determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment. The total payment or charge is calculated to balance the state market risk pool with the goal of encouraging issuers to compete on the basis of price and quality of their plans and not risk selection.

HHS also provides its justification for operating the risk adjustment program in a budget-neutral manner. As part of a budget neutral approach, it uses the statewide average premium as the cost-scaling factor in the transfer formula. HHS chose to use statewide average premium and normalize the risk adjustment state payment transfer formula to reflect state average factors so that each plan's enrollment characteristics are compared to the state average and the calculated payment amounts equal calculated charges in each state market risk pool. Thus, each plan in the risk pool receives a risk adjustment payment or charge designed to compensate for risk as compared to a plan with average risk in a budget-neutral manner.

HHS also proposes to maintain its 14 percent administrative cost reduction to the statewide average premium for the 2021 benefit year as well as the high-cost risk pool parameters: threshold of $1 million and a coinsurance rate of 60 percent for benefit year 2021.

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

In the 2019 Payment Notice, 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.

For the 2021 benefit year, HHS again received a request from Alabama to reduce risk adjustment transfers by 50% for its small group market. 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.

c. Risk Adjustment User Fee for 2021 Benefit Year (§153.610(f))

HHS proposes a risk adjustment user fee for the 2021 benefit year of $0.19 per member per month (PMPM) compared to $0.18 PMPM for the 2020 benefit year. For the 2021 benefit year, HHS proposes to use the same methodology as used for 2020 to estimate a total cost of approximately $50 million to operate the program.

3. Risk Adjustment Data Validation Requirements (§153.630)

Based on HHS' examination of its first two pilot years of risk adjustment data validation (RADV) and its first year of transfer payments, HHS proposes certain amendments and clarifications to the RADV program. As background, HHS conducts RADV in any state where HHS is operating risk adjustment on a state's behalf. The validation consists of an initial validation audit and a second validation audit. Each issuer of a risk adjustment covered plan must engage an independent initial validation audit entity. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to its initial validation auditor for data validation.

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. Application of Risk Adjustment Data Validation Adjustments in Cases where HCC Count is Low

HHS proposes to change the outlier identification process when an issuer has fewer HCCs within an HCC group to be statistically significant. Under the proposed approach, an issuer with fewer than 30 HCCs in an HCC group would not have its risk score adjusted for that group. The scores for the group would, however, continue to be included in the calculation of the overall national metrics.

HHS describes its process for determining outliers and its formulas for calculating the data failure rates for each HCC in an issuers' initial validation sample. It also describes an analysis in which it analyzed smaller and smaller counts of HCCs from which it identified the threshold of 30 HCCs below which the statistical tests for outliers becomes unreliable. HHS notes that it may continue to monitor and improve the RADV methodology as it gains experience and may propose additional methodological changes in the future.

b. Prescription Drugs for the 2019 Benefit Year Risk Adjustment Data Validation

HHS proposes that the 2019 benefit year RADV will serve as a second pilot year for the purpose of prescription drug data validation. HHS needs more time and experience with the prescription drug data before they can be used to adjust risk scores and transfers.

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

1. Verification Process Related to Eligibility for Insurance Affordability Programs

a. Employer-Sponsored Plan Verification

Under existing rules, in determining eligibility for premium tax credits 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 the 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 APTCs or CSRs in error.

As a result, HHS is conducting a study to determine why individuals with available employment-based coverage would seek coverage through Exchanges. The report, which HHS expects to be completed in early 2020, 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 2020 and 2021.

2. Eligibility Redetermination During a Benefit Year (§155.330)

a. Process for Voluntary Termination upon a Finding of Dual Enrollment via Periodic Data Matching

Under existing §155.330(d), Exchanges are required to periodically examine data to determine if an enrollee in a qualified health plan (QHP) who is receiving APTCs or CSRs are eligible for, or enrolled in other qualifying coverage – including in Medicare, Medicaid, CHIP or Basic Health Program plans.

The Exchange must also allow, at the time of plan selection for an enrollee who is determined to be eligible for or enrolled in other coverage during one of those periodic checks, to choose to have their coverage in the QHP terminated. (HHS notes that for the 2019 plan year, Exchanges on the Federal platform could terminate Exchange coverage based on such pre-authorization only for those eligible for or enrolled in Medicare and not for those eligible for Medicaid/CHIP. This is because enrollees in Medicaid/CHIP experience considerably more churn because of fluctuations in income so HHS does not want to increase unnecessary gaps in coverage.)

HHS proposes to amend §155.330(e)(2)(i)(D) to provide that Exchanges need not redetermine eligibility for APTC or CSRs for enrollees who (1) are found to be dually enrolled in QHP coverage and other coverage consisting of Medicare, Medicaid/CHIP, or, if applicable, the BHP, (2) have not responded to the Exchange notice to provide updated information within 30-days, as

required by §155.330(e), and (3) have provided written consent to the Exchange to act to end their QHP coverage via periodic data matching in the event of dual enrollment or eligibility.

b. Effective Date for Termination via Death Periodic Data Matching

Under existing §155.330(e)(2), Exchanges must periodically check available data sources to identify Exchange enrollees who may have become deceased during a plan year. After conducting a redetermination of eligibility, they can be terminated from QHP coverage.

HHS proposes to amend §155.330(e)(2)(i)(D) to clarify that when an Exchange identifies deceased enrollees via periodic data matching, specifically for enrollees who do not respond or contest the updated information within a 30-day period, the Exchange will terminate coverage retroactively to the date of death, without a need to redetermine the eligibility of the deceased enrollee.

3. Automatic Re-enrollment Process

In Exchanges using the Federal platform during the open enrollment period, enrollees in QHPs are able to re-enroll in their current plan, can select a new plan, or can take no action and be re-enrolled in their current plan (or a similar plan if their current plan is no longer available.)

Past commenters have strongly supported automatic re-enrollment for those enrollees taking no action and the U.S. Congress recently enacted a requirement that HHS maintain automatic re-enrollment for the 2021 plan year[8], HHS is concerned about program integrity since automatic re-enrollment could lead to incorrect spending for APTCs. HHS sees this risk as particularly associated with individuals re-enrolled in plans with APTCs which cover the entire plan premium.

As a result, HHS proposes to modify the automatic re-enrollment process so that any enrollee who would under existing rules be automatically re-enrolled in their plan with an APTC covering the entire premium would instead be re-enrolled without any APTC. HHS is also considering a variation of this approach in which the person would be re-enrolled but the APTC would be reduced to a level requiring some premium contribution -- but the APTC would not be entirely eliminated.

HHS believes this proposal would not be a violation of section 608 of H.R. 1865 and notes that if finalized, it would conduct consumer outreach and education to provide warning to enrollees that could include fact sheets or email and would provide education for issuers, agents, brokers, Navigators and other assisters. HHS also notes that existing rules at §155.335 provide Exchanges with some flexibility to establish their own annual redetermination processes and **solicits comments on whether the proposed changes should be mandatory for all Exchanges or if states operating their own eligibility platforms should continue to have flexibility to apply their own processes in these instances.**

[8] Section 608 of H.R. 1865 (P.L. 116-94), the Further Consolidated Appropriations Act, 2020, passed on December 20, 2019.

4. Special Enrollment Periods (§155.420)

a. Exchange Enrollees Newly Ineligible for Cost-Sharing Reductions

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. Under these rules, enrollees and their dependents who become newly eligible for CSRs must be permitted to change to a silver-level QHP so they can access those CSRs.

HHS notes that there is no corresponding provision for enrollees and their dependents who lose eligibility for CSRs to change to a non-silver metal level plan which may be more affordable without CSRs. In response to this omission, HHS is proposing to re-designate §155.420(a)(4)(ii) as (a)(4)(ii)(A) and add a new §155.420(a)(4)(ii)(B) permitting enrollees and their dependents who become newly ineligible for CSRs who are enrolled in a silver-level QHP, to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment in an Exchange. In addition, a conforming change would be made to §155.420(a)(4)(iii) to enable those enrollees and dependents to choose a different metal level QHP.

b. Special Enrollment Period Limitations for Enrollees who are Dependents

Existing special enrollment period rules allow for enrollees who gain a dependent to add the dependent(s) to their current QHP or enroll the dependent in a separate QHP. If the business rules of the enrollee's current plan do not permit the dependent to be added, the Exchange must allow the enrollee and dependents to change to another QHP within the same level of coverage (or one metal level higher or lower if another plan at the same metal level isn't available.)

HHS points out that there are certain gaps in the rules so that adding certain family members is not permitted and proposes changes to address them. The rules do not address the situation where the dependent is the enrollee and the newly eligible individual is the parent.

To address this gap, HHS proposes new §155.420(a)(4)(iii)(C) to require an Exchange to allow a qualified individual who is not an enrollee, who qualifies for a special enrollment period and has one or more dependents who are enrollees, to add him or herself to a dependent's current QHP. Parallel to existing rules, if the QHP's business rules do not allow the qualified individual to enroll in such coverage, then he or she may enroll with his or her dependent(s) in another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available).

c. Special Enrollment Period Prospective Coverage Effective Dates

Under existing special enrollment period rules, Exchanges must ensure a coverage effective date of the first day of the following month for individuals choosing a QHP between the 1st day and the 15th of a month. They must ensure a coverage effective date of the first day of the *second*

following month for individuals who select a QHP between the 16th and the last day of any month. HHS points out that this could result in up to a six or seven-week gap in coverage if a person chooses a plan in the middle of a month and the coverage does not begin until the first day of the second following month. HHS notes that most issuers do not take that long to process new enrollments and instead effectuate coverage much more quickly. Further, under existing §155.420(b)(3), state Exchanges have the option to require earlier effective dates for special enrollments.

HHS proposes to clarify existing §155.420(b)(3) making clear that all Exchanges may provide for earlier coverage effective dates for a QHP selection under a special enrollment period.

d. Special Enrollment Period Retroactive Coverage Effective Dates (§155.400(e)(1)(iv))

HHS proposes to eliminate existing §155.400(e)(1)(iv) which establishes a special retroactive effective date binder payment rule for when a special enrollment period verification is prolonged. Under that existing rule, when a special enrollment verification is prolonged, resulting in a potential retroactive eligibility date that is more than 1 month in the past, the enrollee could choose to effectuate coverage for a shorter retroactive period by moving forward one month. Their binder payment would then be a smaller amount. This addresses concerns that prospective enrollees would have difficulty paying for multiple months of retroactive coverage at the same time as needing to pay for one month of prospective coverage.

HHS contends that this special rule is no longer necessary because special enrollment verification periods are seldom prolonged. It notes that in 2017, HHS averaged a response time of 1 to 3 days to review special enrolment verification documents and provide consumers with a response.

Conforming changes are proposed to §155.420(b)(1) and §155.400(e)(1)(iv). In addition, HHS proposes clarifying changes to §155.420(b)(3) to state more clearly that any consumer who can effectuate coverage with a retroactive effective date, including those whose enrollment is delayed until after special enrollment period verification, has the option to effectuate coverage prospectively only by choosing to only pay for one month of coverage.

e. Enrollees Covered by a Non-calendar Year QSEHRA

Existing §155.420(d)(1)(ii) provides a special enrollment period to employees and dependents who newly gain access to an individual coverage Health Reimbursement Account (HRA) or a qualified small employer health reimbursement arrangement (QSEHRA) to enroll in individual health coverage in order to take advantage of the HRA or QSEHRA.

Because these arrangements sometimes become available on a day other than January 1, the special enrollment period needs to be available annually for such non-calendar year plans. The HRA rule made this clear with respect to HRAs. HHS proposes changes to §155.420(d)(1)(ii) to make the same annual availability of a special enrollment period clear for QSEHRAs.

5. Termination of Exchange Enrollment or Coverage (§155.430)

a. Enrollee-Initiated Terminations upon Finding of Dual Enrollment in Medicare

HHS proposes conforming changes with the provision described above to eliminate the requirement that the Exchange must initiate termination of a Medicare dual enrollee's QHP coverage only after completion of a redetermination process.

b. Effective Dates for Retroactive Termination of Coverage or Enrollment due to Exchange Error

The 2019 Payment Notice made changes to §155.430(d)(2) to allow enrollee-initiated terminations to be effective on the date on which the termination was requested by the enrollees instead of with a 14-day advance notice as previously required. HHS failed to make corresponding changes in §155.430(d)(9) with respect to retroactive terminations due to Exchange errors. HHS proposes to make changes to this section to eliminate the requirement that an enrollee must provide 14 days advance notice to terminate their coverage.

6. Eligibility Pending Appeal

HHS requests feedback on several eligibility appeals questions:

- Retroactive applicability of eligibility pending appeal. While appealing an eligibility decision, an Exchange is required to continue the individual's eligibility pending the outcome of the appeal in accordance with the level of eligibility in effect immediately before the eligibility redetermination being appealed. HHS points out that sometimes an enrollee may wish to be in a different plan pending appeal – for example, while awaiting their redetermination of ineligibility for APTC, they may wish to be in a bronze plan because it is a lower cost option. HHS requests feedback on whether appellants who accept eligibility pending appeal should be able to enroll in any plan or must they continue to be limited as under existing rules – or limited in some other way.
- Timeliness of filing for eligibility pending appeal. HHS notes that under existing rules, an applicant has a period of 90 days following an eligibility determination to appeal that determination but there is no timeline for that individual to request eligibility pending appeal. HHS considered the possibility of establishing a 30-day time limit for such a request. The 30-day period would begin once the Exchange appeals entity notifies the applicant that it has received his or her request for appeal. This timeline could potentially recognize that sometimes it is unclear that a person is requesting eligibility pending appeal at the time that they request the appeal and that a person may want some time to gather information after filing an appeal but before requesting eligibility pending appeal. HHS requests comment on establishing a timeliness standard, whether Exchanges should have flexibility to determine their own timeliness standard, what a reasonable timeliness standard should be, and whether there should be an exception to such a timeliness standard for exceptional circumstances.
- Life events occurring during the pendency of the appeal. HHS notes that existing rules do not address how an Exchange should resolve a pending appeal when the appellant's

circumstances change during the period of appeal in a way that impacts their eligibility. HHS provides an example of a person who is appealing the amount of their APTC and during the appeal has a baby. The new dependent may change the financial circumstances relevant for the determination of their amount of APTC. HHS requests comment on how to address such eligibility changes.

- Impact of eligibility decision on eligibility pending appeal. Appellants granted eligibility pending appeal may ultimately have their eligibility redetermination overturned. When a decision overturns the eligibility redetermination being appealed, under §155.545(c)(1)(ii) the appellant has the option to have the decision implemented retroactively. In cases where the appellant continued to receive APTC and CSRs during the period of appeal, it is possible that the decision makes the appellant eligible for a higher dollar amount of APTC or CSRs than what was provided during the appeal. HHS notes that retroactive implementation of such a decision can be burdensome for issuers who may have to re-process claims, recalculate cost-sharing amounts and out-of-pocket maximums, refund excess premium payments, etc. HHS solicit input on what if any limitations on implementation of a decision when eligibility pending appeal has been granted may be appropriate and under what circumstances.
- Eligibility pending appeal and non-payment of premiums. Under existing rules an issuer can terminate coverage after a 3-month grace period, for enrollees for non-payment of premiums. The regulations, however are not clear about if or how the 3-month grace period applies during periods of eligibility pending appeal. HHS requests comment on this topic.

7. 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 2021, 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 2021, HHS proposes a premium growth estimate of 35.42%, which HHS indicates is 5.0% higher than the 2020 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 30.94% for the 2013-2020 period (or about 4.6% over the estimate of income growth used for the 2013-2019 period).

Taking these factors into account, HHS calculates the 2021 premium adjustment percentage to be equal to 35.42% divided by 30.94% or about 1.0342. As a result, the required contribution percentage for 2021 is equal to 8.0% multiplied by 1.0342 or 8.27%, which reflects a increase of about 0.04 percentage points from 2020.

$$8.00\% \times 1.3542/1.3094 = 8.27\%$$

8. Quality Rating Information Display Standards for Exchanges (§§155.1400 and 155.1405)

Under the PPACA, HHS established the Quality Rating System and the QHP Enrollee Experiences surveys. Regulations at §§155.1400 and 155.1405 describe the information display standards for Exchanges for this information. Display standards for that information as issued in an August 2019 Quality Rating Information Bulletin permitted flexibility for state Exchanges to display their QHP quality rating information with limited state customizations. HHS understands that some states have done so and so is proposing amendments to §§155.1400 and 155.1405 to codify this flexibility for states.

HHS reminds states that they cannot develop their own programs and replace the quality ratings developed by HHS in their entirety.

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

1. Definitions (§156.20)

HHS proposes eliminating the definition of the word "generic" at §156.20 consistent with proposed changes to §156.130(h) as described below.

2. FFE and SBE-FP User Fee Rates for the 2021 Benefit Year (§156.50)

HHS proposes to maintain the user fee rate for 2021 for all participating FFE issuers at 3.0%, which is the same amount required for 2020. This fee reflects the costs of certifying plans as QHPs and selling coverage through the FFE for those determined to be eligible to enroll in a QHP. For states electing to use the Federal Platform for Exchange functions (in which a state chooses use the federal IT platform for certain Exchange functions), HHS likewise proposes to maintain the user fee at 2.5% 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, and is also the same as for 2020.

For both fees, HHS requests comment on alternative amounts that would be lower than the 3.0% and 2.5% amounts proposed. HHS believes that there may be less funding needed for those functions because of lower enrollment and higher premiums. HHS does indicate, though, that if

the reduced needs did not materialize, then user fees might need to be raised in subsequent periods to cover those costs.

HHS seeks feedback on the trends in use of Exchange functions and services and Federal platform functions and services; potential efficiencies in such operations; and premium and enrollment projections.

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

a. Annual reporting of state-required benefits

Under existing law and regulations, state mandated benefits existing prior to December 31, 2011 may be considered to be part of 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 past, Exchanges have been responsible for identifying those additional state mandated benefits requiring defrayal. In response to stakeholder concerns that states may not be defraying the costs of state-required benefits, HHS is proposed to incorporate new state reporting requirements.

HHS proposes adding new paragraph §156.11(d) to establish the requirement for reporting state-required benefits that are in addition to EHB. If the state does not do so, HHS would determine which benefits are in addition to EHB for the applicable plan year.

New paragraph §156.11(f) would establish the details for such reporting. The reports would be required to:

- List those mandated benefits including all of those imposed on issuers up to 60 days prior to the annual reporting submission deadline, identifying those imposed on or before December 31, 2011 (unless they were withdrawn or no longer effective before that date) and those imposed after that date;
- Identify which of those benefits are subject to defrayal;
- Identify which of those benefits are not subject to defrayal and the basis for that determination;
- Include any other information specified by HHS as necessary for oversight;
- Be signed by a state official to certify accuracy; and
- Be updated annually.

HHS states that the first such annual report will be due July 1, 2021. The report would need to identify state benefits established through May 2, 2021. HHS notes that while those benefits mandates imposed after May 2, 2021 do not need to appear in the first annual report, states are

still required under statute to defray the costs of those benefits. The requirement to report does not impact the requirement to defray costs.

HHS intends to provide templates for the reporting and to post state submissions on the CMS website to be available to the public.

HHS solicits comment on the proposed reporting deadline and whether the 60-day cut off timeline should be shortened to 30 days. HHS seeks comment on the extent to which states are not appropriately identifying and defraying state-required benefits in addition to EHB and whether states are the appropriate entities for determining which state required benefits are in addition to EHB. In addition, HHS seeks comment on its proposal to determine such benefits if a state does not provide the annual reporting and whether HHS should allow states to affirmatively decline to report.

b. States' EHB-benchmark plan options

HHS proposes a deadline of May 7, 2021 for states to submit documents for a state's EHB-benchmark plan selection for the 2023 plan year. As in the past, HHS recommends that states submit applications at least 30 days before the submission deadlines to ensure completion and reminds states that the period of public comment must also be completed by the deadlines. The same deadline applies to notification by states that they will permit issuers to substitute benefits between EHB categories. [9]

4. Essential Health Benefits Package

a. 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 2021 is approximately 35%.

HHS continues to use the approach first used for 2020 to calculate the premium adjustment percentage. That approach takes into account in measuring premium growth, the growth of individual market premiums instead of only including the growth of premiums in the employer market for insurance. It is based on published NHEA data and it includes employer-based insurance as well as individual market health insurance both on and off exchanges, but excludes Medigap insurance and the medical portion of accident insurance.

Using the proposed premium adjustment percentage to calculate the maximum annual limitations on cost-sharing for 2021 results in those amounts rising to $8,550 for self-only coverage and $17,100 for other than self-only coverage. This would represent about a 4.9% increase over the amounts for 2020.

[9] Deadlines for submission of required documents for EHB-benchmark plan selection & to notify HHS that issuers may substitute benefits between categories for plan year 2022 is May 8, 2020.

b. 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.[10] Using a process similar to the one used in the 2014 – 2020 Payment Notices, HHS finds that the maximum annual limitation on cost-sharing for people with income between 200% and 250% requires additional adjustment – as it did in 2017, 2018, and 2019. The resulting adjusted maximums proposed for 2021 are as follows:

Eligibility Category	Reduced Maximum Annual Limitation on Cost-sharing for Self-Only Coverage for 2021	Reduced Maximum Annual Limitation on Cost-sharing for Other than Self-Only Coverage for 2021
Individuals eligible for cost-sharing reduction with income between 100 and 150% of FPL	$2,850	$5,700
Individuals eligible for cost-sharing reduction with income between 150 and 200% of FPL	$2,850	$5,700
Individuals eligible for cost-sharing reduction with income between 200 and 250% of FPL	$6,800	$13,600

c. Cost Sharing Requirements (§156.130(h))

Existing rules (at §156.130(h)) permit issuers to exclude amounts paid toward cost sharing using copay cards or other types of direct support from manufacturers for drugs with generics available from annual limitations on cost sharing. This provision has raised confusion as to whether, when generics are not available, issuers are required to count the value of the copay coupons toward the annual limitations on cost sharing. It is particularly confusing in light of recent FAQs issued by HHS and the Departments of Labor and Treasury which instruct a high-deductible health plan (HDHP) issuer to disregard drug discounts and manufacturer or provider discounts when determining if the deductible for an HDHP has been satisfied.[11]

HHS proposes to revise §156.130(h) to clarify that amounts paid toward reducing the cost sharing incurred by an enrollee using any form of manufacturer direct support may be, but are not required to be, counted toward the annual limitation on cost sharing. The amendment would clarify that issuers and group health plans have the flexibility to determine whether to include or exclude

[10] 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.
[11] Q&A-9 of IRS Notice 2004-50.

coupon amounts from the annual limitation on cost sharing regardless of whether or not a generic is available.

HHS continues to encourage issuers and group health plans to address the market distortion that occurs when consumers select a higher-cost brand name drug when an equally effective, medically appropriate generic is available.

5. Requirements for Timely Submission of Enrollment Reconciliation Data (§156.265)

Under existing rules, issuers are required to reconcile enrollment with Exchanges no less than once a month. There are no standards, however, for the format or quality of those data exchanges. HHS proposes to include such standards as amendments to §156.265 (f) and (g) to encourage more timely reconciliation and error reporting. HHS proposes to amend:

- Paragraph (f) to require an issuer to include in its enrollment reconciliation submission to the Exchange, the most recent enrollment information available that has been verified to the best of its knowledge or belief; and
- Paragraph (g) to direct QHP issuers to update their enrollment records and inform the Exchange if any such records contain errors, within 30 days.

6. Promoting Value Based Insurance Design

HHS proposes to offer QHPs the option to design a value-based insurance plan that would include the coverage of high-value services at lower cost-sharing amounts and lower-value services at higher cost-sharing amounts. While issuers have a great deal of flexibility to incorporate value-based design features in their QHPs, HHS outlines a "value-based" model QHP identifying specific high- and low-value services. Table 11, reproduced below, lists high-value services and drugs that an issuer may want to consider offering with lower or zero cost sharing as well as low-value services that issuers should consider setting at higher cost-sharing. It is based on work done by the Center for Value-based Insurance Design at the University of Michigan.

HHS believes that a silver metal level plan could incorporate the features as proposed in Table 11 without impacting plan premiums.

HHS is not proposing to offer preferential display on HealthCare.gov for value-based model plans but seeks feedback on how consumers could identify a value-based QHP. **In addition, HHS seeks feedback in the following areas:**

- **How to communicate the availability of value-based QHPs to consumers and how their features would affect different consumers;**
- **How to assist consumers in selecting a value-based QHP if appropriate;**
- **How HHS could collect information from issuers in Exchanges using the Federal platform to indicate that their QHP includes value-based design and what additional standards HHS should adopt for value-based plans (e.g. minimum standards), as well as any obstacles to implementation;**
- **How HHS could provide operational assistance to issuers wishing to offer value-based QHPs;**
- **State cost sharing laws that would not allow for this type of plan design; and**

- **Other value-based insurance design activities HHS should pursue in the future, including models for stand-alone dental plans.**

Table 11: High and Low Value Services and Drug Classes

High Value Services with Zero Cost Sharing	Specific low value services Considered
Blood pressure monitors (hypertension)	Proton beam therapy for prostate cancer
Cardiac rehabilitation	Spinal fusions
Glucometers and testing strips (diabetes)	Vertebroplasty and kyphoplasty
Hemoglobin a1c testing (diabetes)	Vitamin D testing
INR testing (hypercoagulability)	**Commonly overused service categories with Increased Cost-sharing**
LDL testing (hyperlipidemia)	Outpatient specialist services
Peak flow meters (asthma)	Outpatient labs
Pulmonary rehabilitation	High-cost imaging
High Value Generic Drug Classes with Zero Cost Sharing	X-rays and other diagnostic imaging
ACE inhibitors and ARBs	Outpatient surgical services
Anti-depressants	Non-preferred branded drugs
Antipsychotics	
Anti-resorptive therapy	
Antiretrovirals	
Antithrombotics/anticoagulants	
Beta blockers	
Buprenorphine-naloxone	
Glucose lowering agents	
Inhaled corticosteroids	
Naloxone	
Rheumatoid arthritis medications	
Statins	
Thyroid-related	
Tobacco cessation treatments	
High Value Branded Drug Classes with Reduced Cost Sharing	
Anti-TNF (tumor necrosis factor)	
Hepatitis C directing-acting combination	
Pre-exposure prophylaxis for HIV (PrEP)*	

Notes:
*Per 26 CFR 54.9815-2713, 29 CFR 2590.715-2713 and 45 CFR 147.130, non-grandfathered group health plans and non-grandfathered health insurance coverage in the group or individual markets, including QHP issuers in the individual market, will be required to cover PrEP without imposing any cost-sharing requirements for plan or policy years beginning on or after June 30, 2020, in a manner consistent with the U.S Preventive Services Task Force (USPSTF) final recommendation at https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis

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

HHS proposes a change to make clear that termination notices are required whenever there is a termination described in §155.430(b) –which includes terminations initiated by enrollees as well as those initiated by Exchanges. The proposed change addresses confusion from issuers regarding when termination notices are required.

8. 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 the report. Issuers have 15 days to do so under those rules. HHS proposes to extend the timeframe for issuers to respond to those reports to 90 calendar days from the date of the report. HHS notes that the change is in response to learning that issuers are not automatically able to respond to the reports, and some prefer to research payment errors which can take longer than 15 days.

In addition, HHS proposes to remove the requirement that issuers confirm payment accuracy to HHS each month and eliminate a provision addressing discrepancies identified after the 15 day timeline ends. Instead HHS proposes a new §156.1210(b) to require an annual confirmation report after the end of each payment year.

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

1. Reporting Requirements Related to Premiums and Expenditures (§158.110)

HHS proposes changes to the reporting requirements for medical loss ratio (MLR) reporting. HHS states that the purpose of the proposed changes is to clarify the treatment of expenses for clinical and administrative functions outsourced to other entities. Issuers have raised questions about the rules when the outsourced activities are clinical rather than administrative activities.

HHS reviews a series of earlier guidances that addresses the treatment of various types of outsourced activities:

- May 2011[12] Q&A #12 clarified that issuers can include payments to third-party vendors attributable to direct provision of clinical services in incurred claims;
- May 2011 Q&A #8 states the inclusion of a third-party vendor's administrative costs as incurred claims is only permitted to the extent the vendor is reimbursed under a capitation arrangement, which is consistent with how capitation payments to providers are treated for MLR purposes.
- May 2011 Q&A #14 clarified that payments to third-party vendors for expenses incurred when performing health care Quality Improvement Activities (QIA) can be reported as QIA but those amounts cannot include the vendor's administrative costs or profits;

[12] CCIIO Technical Guidance (CCIIO 2011—002): Questions and Answers Regarding the Medical Loss Ratio Interim Final Rule at https://www.cms.gov/CCIIO/Resources/Files/Downloads/mlr-guidance-20110513.pdf.

- July 2011 CCIIO Technical Guidance[13] Q&A #19 clarified that payments to third-party vendors can only be included in incurred claims to the extent the vendor provides clinical services through its own employees, and that payments to the vendor to perform administrative functions on behalf of the issuer must be reported as non-claims administrative expenses.

The proposed change is intended to make clear that expenses for functions outsourced to, or provided by, other entities must be reported consistently with how such expenses would be reported if they had been incurred directly by the issuer.

2. Reimbursement for Clinical Services Provided to Enrollees (§158.140)

HHS proposes to revise §158.140(b)(1)(i) to add to the adjustments that must be deducted from incurred claims for the purpose of MLR reporting. In addition to the existing adjustments for prescription drug rebates and price concessions received by the issuer, HHS would also require deductions for any prescription drug rebates or other price concessions received and retained by an entity providing pharmacy benefit management services (including drug price negotiation services).

HHS also proposes conforming changes to §158.160(b)(2) to require issuers to report the prescription drug rebates and price concessions as non-claims costs.

HHS proposes to make these changes to increase the likelihood that enrollees receive the benefit of prescription drug rebates and price concessions. It would also to address an inequity in which issuers benefit from compensating pharmacy benefit managers by allowing them to keep prescription drug rebates or price concessions -- which inflates incurred claims and MLRs -- whereas financially identically situated issuers who compensate PBMs by paying a fee or an inflated pharmacy reimbursement amount are at a disadvantage.

HHS points out that the proposed amendment would provide a more equitable treatment of issuers in the commercial health insurance markets and would also align MLR provisions more closely with those applicable to Medicare Advantage plans and Medicaid managed care plans, both of which require that the full amount of prescription drug rebates and price concessions be deducted from incurred claims.

HHS proposes that the amendments would apply beginning with the 2021 MLR reporting year (reports due by July 31, 2022). **It seeks comments on the start date and whether issuers would have adequate time to adjust contracts and establish processes to collect information about such rebates and price concessions.**

3. Activities that Improve Health Care Quality (§158.150)

HHS proposes a clarification in §158.150(b)(2)(iv)(A)(5) that issuers in the individual market may include the cost of wellness incentives as QIA expenses in the MLR calculation in the same

[13] CCIIO Technical Guidance (CCIIO 2011—004): Questions and Answers Regarding the Medical Loss Ratio Interim Final Rule, https://www.cms.gov/CCIIO/Resources/Files/Downloads/20110718_mlr_guidance.pdf.

manner as permitted for the group market. The amendment would be applicable beginning with the 2021 MLR reporting year (reports due by July 31, 2022).

IV. Collection of Information Requirements

HHS identifies three 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.

- The proposed notice requirement for excepted benefit HRAs offered by non-federal government plan sponsors is estimated to result in a total aggregate burden of about $182,000 in the first year. Of this estimate, $177,569 would result from one-time costs of preparing the notice and $4,445 from the annual cost of printing notices for distribution to eligible participants. (HHS assumes that 54 percent of the notices would be provided electronically.) These estimated costs would be spread among the 901 state and local government employers (with a total of 193,715 employees) that are estimated to offer excepted benefit HRAs each year. The average total cost over 3 years, shown in proposed rule Table 14, would be $63,645. HHS notes that comments are sought on limiting the requirement to plan years for which the terms of the excepted benefit HRA are changed. If such a limit is finalized, the impact would be lower.
- The proposal to require states to annually report to HHS on any state-required benefits applicable to the individual or small group markets that are considered in addition the EHBs under §155.170 would result in a small burden on states under the estimates. Because states must already identify these benefits HHS believes the information is readily accessible. It estimates that the cost per state to comply with the proposed new reporting requirement would be $2,459 in the first year and $1,117 for subsequent years when only updating would be needed. HHS assumes 41 states would comply with this requirement for an aggregate cost of $100,829 in the first year and $45,817 in subsequent years. The average aggregate cost over 3 years, shown in Table 14, is estimated at $64,154.
- No dollar estimate is provided for the documentation requirements associated with the proposal to allow individuals provided a QSEHRA on a non-calendar year basis to qualify for the existing special enrollment period. Under the proposal, these qualifying individuals would have to provide supporting documentation of the end date of their QSEHRA. HHS estimates that few additional consumers would be required to submit documents under this proposal because it involves only the subset of consumers with a QSEHRA that renews on a non-calendar year basis who wish to enroll in or change plans mid-calendar year. HHS believes that few consumers will opt to change plans in the middle of a calendar year because deductibles and cost sharing would be reset; comments are sought on whether or not this is the case.

In addition, HHS estimates that the proposed amendments to the medical loss ratio requirements would not require changes to existing reporting forms or significantly change the reporting burden. HHS further states that existing burden estimates for QHP issuers already account for the required notice to enrollees when coverage is terminated, and no changes are proposed to the

submission process or burden as a result of the proposal to require issuers to send termination notices to enrollees for all termination events.

Public comments on potential information collection requirements are invited. **The deadline for comments on the information collection requirements is April 6, 2020.**

V. 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.

HHS states that the proposed rule aims to ensure taxpayer money is more appropriately spent and that states have flexibility and control over their insurance markets. Benefits would be reduced regulatory burden, reduced administrative costs for issuers and states, and lower net premiums for consumers resulting in increased access to affordable health coverage. States and other affected entities would incur costs related to the EHB reporting requirement, and implementation of new special enrollment period requirements. Non-federal plan sponsors offering excepted benefit HRAs would incur expenses associated with providing a notice. Issuers would pay more in rebates to consumers due to proposed amendments to the MLR requirements. In accordance with Executive Order 12866, HHS believes that the potential benefits of the proposed rule justify the costs.

Table 15 of the proposed rule summarizes HHS' assessment of the qualitative impacts and estimated direct monetary costs and transfers that would result from the proposals. The total cost for HHS to operate the risk adjustment program for 2021 is estimated to be approximately $50 million, similar to the cost for 2020, and the proposed risk adjustment user fee is $0.19 PMPM. (As discussed elsewhere in the proposed rule, HHS is considering alternative user fee proposals.)

HHS does not expect the proposed rule to change the budget effect of the premium stabilization programs, which are summarized in Table 16 of the proposed rule. That table presents the Congressional Budget Office estimates from May 2019, showing collections and payments for the premium stabilization programs each totaling $29 billion for the period 2020-2024. HHS says that its own analyses conclude that the proposed rule effects are consistent with the estimates it provided in the 2020 Payment Notice with respect to the APTCs, the premium stabilization programs, and FFE user fee requirements.

Proposed changes to the MLR requirements are estimated to increase issuer rebates to consumers by $18.2 million per year. In addition, HHS notes that premiums and premium tax credits may decrease as a result of these changes.

HHS discusses the estimated savings to Exchanges from the proposal it intends to make in future rulemaking 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 one-time savings of $44 million and $92 million operational savings in 2020 and 2021 would be shared across that the Exchanges using the federal platform and most state exchanges.

As discussed above, HHS estimates that the costs associated with collection of information requirements would total $283,000 in 2020 and $50,000 annually thereafter. Finally, the aggregate cost of reading and understanding the proposed rule is estimated to be $54,000 in 2020; this estimate assumes it takes one hour of staff time to review the rule.

The qualitative benefits and costs listed in Table 15 and discussed by HHS include greater market stability from updates to the risk adjustment methodology; strengthened program integrity related to proposals to terminate QHP coverage for Exchange enrollees who die during a plan year and those who have authorized voluntary terminations when data matching reveals dual eligibility or enrollment, ; increased continuous coverage and associated benefit to risk pools from more plan options for Exchange enrollees newly ineligible for CSRs; streamlined Exchange operations from eliminating prospective coverage effective date rules and retroactive payment rules for special enrollment periods; potential savings to issuers from elimination of duplicative coverage as part of PDM; potential savings to consumers from efforts to notify enrollees of duplicative coverage and risk for tax liability; potential costs to Exchanges and consumers to comply with the proposed new special enrollment period requirements; and potential savings to Exchanges and issuers from proposed changes to special enrollment period effective dates. HHS seeks comments on its conclusions and expectations regarding these potential effects.