

Supporting Statement for Paperwork Reduction Act Submissions: Standards Related to Reinsurance, Risk Corridors, Risk Adjustment, and Payment Appeals (CMS-10401/OMB Control Number 0938-1155)

A. Background

The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 [collectively, the “Patient Protection and Affordable Care Act” (ACA)], provided for three premium stabilization programs – a transitional reinsurance program, a temporary risk corridors program, and a permanent risk adjustment program (the 3Rs programs) – to mitigate the negative impacts of adverse selection and market uncertainty. This document focuses on the data collection requirements related to the 3Rs programs.

1. Transitional Reinsurance Program

Established by Section 1341 of the ACA, the transitional reinsurance program was applicable for the 2014–2016 benefit years. Currently, close-out activities continue for this program, and are expected to continue into 2023 or beyond, as required.

2. Temporary Risk Corridors Program

Established by Section 1342 of the ACA, the temporary risk corridors program was applicable for the 2014–2016 benefit years. No close-out activities remain for the risk corridors program.

3. Permanent Risk Adjustment Program

Established by Section 1343 of the ACA, the permanent risk adjustment program transfers funds from lower risk, non-grandfathered plans to higher risk, non-grandfathered plans in the individual and small group markets, inside and outside the Exchanges. Some notable changes to the risk adjustment program are as follows:

- EDGE Data Collection

In the HHS Notice of Benefit and Payment Parameters for 2023 final rule (“2023 Payment Notice,” 87 FR 27208), we finalized the EDGE data extraction and collection requirements to include five new data elements for collection: 1) ZIP code, 2) Race, 3) Ethnicity, 4) Subsidy Indicator, 5) Individual Coverage Health Reimbursement (ICHRA) Indicator as well as the collection of extracted HIOS ID and rating area data elements (87 FR 27208 at 27241). In the HHS Notice of Benefit and Payment Parameters for 2024 final rule (“2024 Payment Notice,” 88 FR 25740), we added a sixth new EDGE data element for collection: Qualified Small Employee Health Reimbursement Arrangement (QSEHRA) Indicator (88 FR 25781).

- High-Cost Risk Pool

In the 2023 Payment Notice (87 FR 27208 at 27253), we finalized that whenever HHS recoups high-cost risk pool funds as a result of audits of risk adjustment covered plans, actionable discrepancies, or successful appeals, the recouped funds will be used to reduce high-cost risk pool charges for that national high-cost risk pool for the next applicable benefit year for which high-cost risk pool payments have not already been calculated.

- Risk Adjustment Transfers Reduction

In the 2023 Payment Notice (87 FR 27208 at 27236), HHS repealed the ability of states to request a reduction in risk adjustment state transfers starting with the 2024 benefit year, with an exception for prior participants until the 2025 benefit year. In the 2024 Payment Notice (88 FR 25740 at 25776), HHS repealed the ability of prior participants to request a reduction in risk adjustment state transfers starting with the 2025 benefit year.

- *Risk Adjustment Data Validation*

In the 2023 Payment Notice (87 FR 27208 at 27253), HHS finalized refinements to the HHS–RADV error estimation methodology beginning with the 2021 benefit year to: (1) Extend the application of Super hierarchical condition categories (HCCs) from their application only in the sorting step that assigns HCCs to failure rate groups to broader application throughout the HHS–RADV error rate calculation process; (2) specify that Super HCCs will be defined separately according to the age group model to which an enrollee is subject, except when the child and adult coefficient estimation groups have identical definitions; and (3) constrain to zero any failure rate group outlier with a negative failure rate, regardless of whether the outlier issuer has a negative or positive error rate. In the 2024 Payment Notice (88 FR 25740 at 25788), HHS finalized the revision of the materiality threshold for random and targeted sampling beginning with the 2022 benefit year, changing the materiality threshold from \$15 million in total annual statewide premiums to 30,000 total statewide billable member months (BMM). In the 2024 Payment Notice, HHS also finalized the repeal the exemption of exiting issuers from adjustments to risk scores and risk adjustment transfers in cases where the exiting issuer was a negative error rate outlier, beginning with 2021 benefit year HHS–RADV.

The regulatory history of the 3Rs programs is as follows:

- Standards Related to Reinsurance, Risk Corridors and Risk Adjustment (“Premium Stabilization Rule,” 77 FR 17220): On March 23, 2012, HHS published the Premium Stabilization Rule to implement and set standards for the reinsurance, risk corridors, and risk adjustment programs.
- HHS Notice of Benefit and Payment Parameters for 2014 final rule (“2014 Payment Notice,” 78 FR 15410): On March 11, 2013, HHS published the 2014 Payment Notice to implement requirements for various programs established by the ACA, including the risk adjustment program in states where HHS operates risk adjustment, and to expand on standards related to the 3Rs programs set forth in the Premium Stabilization Rule. This rule also finalized six steps for error estimation for HHS–RADV and further clarified HHS–RADV policies.
- Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards (“Program Integrity Rule II,” 78 FR 65046): On October 30, 2013, HHS published the Program Integrity Rule II to outline financial integrity and oversight standards with respect to state-operated risk adjustment and reinsurance programs, including provisions governing reporting requirements and restricting the use of reinsurance funds for administrative expenses. HHS also amended the risk adjustment payment transfer formula in order to accommodate community rated states that utilized family tiering rating factors.
- HHS Notice of Benefit and Payment Parameters for 2015 final rule (“2015 Payment Notice,” 79 FR 13743): On March 11, 2014, HHS published the 2015 Payment Notice to expand upon, modify, and clarify the provisions of the Premium Stabilization Rule and the

2014 Payment Notice, including to reduce issuers' sample size for HHS-RADV, and the first and second Program Integrity Rules (78 FR 54070 and 78 FR 65046). HHS also finalized HHS–RADV requirements related to sampling; IVA standards, SVA processes, and medical record review as the basis of enrollee risk score validation; the error estimation process and original methodology; and HHS–RADV appeals, oversight, and data security standards.

- HHS Notice of Benefit and Payment Parameters for 2016 final rule (“2016 Payment Notice,” 80 FR 10750): On February 17, 2015, HHS published the 2016 Payment Notice to extend the good faith safe harbor for non-compliance with the HHS-operated risk adjustment and reinsurance data requirements through the 2015 calendar year. HHS also explained that if, in the last year of the risk corridors program, there were excess cumulative risk corridors collections that exceeded the cumulative risk corridors payments owed, HHS would implement an adjustment to the profit floor and administrative cost ceiling to increase risk corridors payments for eligible issuers for benefit year 2016.
- HHS Notice of Benefit and Payment Parameters for 2017 final rule (“2017 Payment Notice,” 81 FR 12204): On March 8, 2016, HHS published the 2017 Payment Notice to update the risk adjustment factors to reflect multiple years of claims data to better address any data lag and more accurately account for conditions with high-cost treatments. In addition, beginning with the 2017 benefit year, HHS recalibrated the risk adjustment model to trend specialty and traditional drug expenditures at separate growth rates from medical expenditures and incorporated preventive services into the simulation of plan liability. To encourage continued compliance with risk adjustment data submissions, beginning with the 2015 benefit year, HHS raised the default risk adjustment charge from the 75th percentile to the 90th percentile of absolute transfers nationwide as a percent of state average premium.
- HHS Notice of Benefit and Payment Parameters for 2018 final rule (“2018 Payment Notice,” 81 FR 94058): On December 22, 2016, HHS published the 2018 Payment Notice which provided that beginning for the 2018 benefit year, to allow for risk adjustment transfers to be calculated based on the portion of statewide average premiums that reflects enrollees' risk and not fixed administrative costs, HHS finalized an adjustment to reduce the calculation of statewide average premium used in the risk adjustment transfer formula by 14 percent to account for fixed administrative costs. HHS also updated the risk adjustment methodology to incorporate enrollment duration factors and prescription drug categories; adjusted for extremely high-cost enrollees through the incorporation of the high-cost risk pool; provided the authority for use of masked enrollee-level EDGE server data collected for actual risk adjustment calculations for calibration of HHS programs, including the Actuarial Value (AV) calculator and to better understand these markets; and updated EDGE server data collection by including two new data elements: (1) regarding pharmacy claims, the number of days' supply (Days Supply) for prescription drugs, and (2) regarding pharmacy and medical claims, a Claims In-Network or Out-of-Network Indicator. HHS also provided that issuers of plans with 500 or fewer billable member months statewide would be exempt from hiring an initial validation auditor for HHS-RADV. HHS also established a discrepancy process and clarified certain aspects of the administrative appeals process for HHS-RADV.
- HHS Notice of Benefit and Payment Parameters for 2019 final rule (“2019 Payment Notice,” 83 FR 16930): On April 17, 2018, HHS published the 2019 Payment Notice

where HHS postponed the \$15 million materiality threshold for HHS-RADV audits until 2018 benefit year HHS-RADV. HHS also permitted state regulators to request a reduction in the statewide average premium factor of the risk adjustment transfer formula, beginning with the 2020 benefit year. In addition, for 2017 benefit year HHS-RADV and beyond, HHS finalized an amended error estimation methodology to only adjust issuers' risk scores when an issuer's failure rate is materially different from other issuers based on three hierarchical condition category (HCC) groupings (low, medium, and high), that is, when an issuer is identified as an outlier. HHS also finalized a requirement that initial validation audit (IVA) samples only include enrollees from state market risk pools with more than one issuer; clarifications regarding civil money penalties for non-compliance with HHS-RADV; a process to handle demographic or enrollment errors discovered during HHS-RADV; and an exception to the prospective application of HHS-RADV results for exiting issuers, such that exiting outlier issuers' results are used to adjust the benefit year being audited (rather than the following transfer year). In addition, starting with the 2017 benefit year HHS-RADV, HHS permitted issuers to provide mental and behavioral health assessments rather than full medical records, as was previously required, for purposes of validating a diagnosis in HHS-RADV.

- HHS Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 benefit year ("2018 RA Rule 1," 83 FR 36456): On July 30, 2018, HHS published the 2018 RA Rule 1 that adopted the 2017 benefit year HHS-operated risk adjustment methodology set forth in the Premium Stabilization Rule and the 2017 Payment Notice. This rule set forth additional explanation of the rationale supporting the use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including why the program is operated in a budget-neutral manner, and permitted HHS to resume 2017 benefit year program operations, including collection of risk adjustment charges and distribution of risk adjustment payments.
- Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year Final Rule ("2018 RA Rule 2," 83 FR 63419): On December 10, 2018, HHS published the 2018 RA Rule 2 to adopt the 2018 benefit year HHS-operated risk adjustment methodology as established in the Premium Stabilization Rule and 2018 Payment Notice, which permitted HHS to resume 2018 benefit year program operations, including collection of risk adjustment charges and distribution of risk adjustment payments.
- HHS Notice of Benefit and Payment Parameters for 2020 final rule ("2020 Payment Notice," 84 FR 17454): On April 25, 2019, HHS published the 2020 Payment Notice to, beginning with the 2018 benefit year, incorporate prescription drugs into HHS-RADV as a method of discovering materially incorrect EDGE data submissions, pilot the process of including prescription drugs into HHS-RADV for the 2018 benefit year, and finalize policies related to the application of issuer risk score error rates when an issuer exits all markets in a state or joins a previously single-issuer market. In addition, HHS established exemptions from HHS-RADV for issuers in liquidation who meet certain conditions, sole market risk pool issuers, and small group market issuers with off-calendar year coverage who exit the market but have only carry-over coverage that ends in the next benefit year. HHS also finalized a policy to create on an annual basis an Enrollee-Level EDGE Limited Data Set (LDS) using masked enrollee-level data submitted to EDGE servers by issuers of

risk adjustment covered plans in the individual and small group (including merged) markets, and make this dataset available to requestors who seek the data for research purposes. Additionally, HHS finalized its proposal related to HHS-RADV to extend the Neyman allocation sampling methodology to the 10th stratum of enrollees without HCCs so that all 10 strata use this methodology.

- HHS Notice of Benefit and Payment Parameters for 2021 final rule (“2021 Payment Notice,” 85 FR 29164): On May 14, 2020, HHS published the 2021 Payment Notice to finalize that, beginning with the 2021 benefit year, risk adjustment would blend the three most recent years of available enrollee-level EDGE data, and beginning with the 2019 benefit year HHS-RADV, HHS would not consider an issuer with fewer than 30 HCCs within an HCC failure rate group to be an outlier for that HCC failure rate group. Also, HHS established that it would continue to pilot the validation of prescription drug categories into HHS–RADV for the 2019 benefit year.
- Amendments to the HHS-Operated Risk Adjustment Data Validation (HHS–RADV) Under the Patient Protection and Affordable Care Act’s HHS-Operated Risk Adjustment Program (“HHS-RADV Amendments Rule,” 85 FR 76979): On December 1, 2020, HHS published the HHS-RADV Amendments Rule, beginning with the 2019 benefit year for states where HHS operates the risk adjustment program, to adopt a sliding scale adjustment to address a concern that issuers with failure rates that are just outside of the confidence intervals receive an adjustment to their risk scores, even though these issuers’ failure rates may not be significantly different from the failure rates of issuers just inside the confidence intervals who receive no risk score adjustment. In addition, HHS finalized the adoption of Super HCCs in the sorting of HCCs into failure rate groups, and HHS modified the error rate calculation in cases where a negative failure rate outlier issuer has a negative error rate overall. HHS also finalized that HHS-RADV adjustments to risk scores and risk adjustment transfers would be applied to the same benefit year being audited, transitioning from the prospective application of the HHS-RADV results to a concurrent application of the HHS-RADV results for the benefit year being audited. To effectuate the transition, for the 2020 benefit year of risk adjustment, HHS made payment adjustments using the simple average of 2019 and 2020 benefit year HHS-RADV results. Starting with the 2021 benefit year of risk adjustment onward, HHS will make payment adjustments using HHS-RADV audit data for the same benefit year (i.e. the HHS-RADV audit is now conducted on a concurrent basis).¹
- HHS Notice of Benefit and Payment Parameters for 2022 final rule (“2022 Payment Notice,” 86 FR 24140): On May 5, 2021, HHS published the 2022 Payment Notice to finalize risk adjustment reporting requirements for issuers of risk adjustment covered plans who choose to provide temporary premium credits, if permitted by HHS during a future public health emergency, and to clarify the calculation of HHS risk adjustment payment and charges in light of these premium credits by specifying that, for states where issuers of risk adjustment covered plans provide temporary premium credits when permitted by HHS, the plan average premium and statewide average premium used in the state payment transfer formula would be calculated using issuers’ adjusted premium amounts. HHS also finalized the policy to use the three most recent consecutive years of enrollee-level EDGE data that are available in time for incorporating into the coefficients in the proposed rule

¹ See the 2020 HHS-RADV Amendments Rule, 85 FR 77002 through 77005.

and to not update the coefficients for additional years of data between the proposed and final rules if an additional year of enrollee-level EDGE data becomes available.

- HHS Notice of Benefit and Payment Parameters for 2023 final rule (“2023 Payment Notice,” 87 FR 27208): On May 6, 2022, HHS published the 2023 Payment Notice to finalize two updates to the risk adjustment models beginning with the 2023 benefit year. First, HHS finalized the removal of the current severity illness factors from the adult models and the addition of an interacted hierarchical condition category (HCC) count model specification to the adult and child models. Second, HHS replaced the current enrollment duration factors in the adult models with HCC-contingent enrollment duration factors. In the 2023 Payment Notice (87 FR 27236), HHS finalized the repeal of the ability of states, other than “prior participants,” to request a reduction in risk adjustment state transfers starting with the 2024 benefit year, and changes that limit a prior participant’s ability to request a reduction in risk adjustment transfer to only those that meet the de minimis threshold framework and criteria. In addition, HHS finalized extracting existing EDGE data elements including plan ID and rating area beginning with the 2021 benefit year and subscriber indicator beginning with the 2022 benefit year. Beginning with the 2023 benefit year, HHS finalized proposals to collect and extract ZIP Code, race, ethnicity, an ICHRA indicator, and a subsidy indicator as part of the risk adjustment data issuers of risk adjustment covered plans are required to make accessible to HHS on their EDGE servers in states where HHS operates the risk adjustment program. For the 2023 and 2024 benefit years, HHS adopted a transitional period for the race, ethnicity, and ICHRA indicator fields, during which time issuers will be required to populate these fields using available data sources. Then, beginning with the 2025 benefit year, issuers that do not have an existing source to populate these fields for particular enrollees will be required to make a good faith effort to collect and submit race, ethnicity, and ICHRA indicator data elements for these enrollees. HHS also finalized further refinements to the HHS-RADV error rate calculation methodology beginning with the 2021 benefit year and beyond to: (1) Extend the application of Super HCCs from their current application only in the sorting step that assigns HCCs to failure rate groups to broader application throughout the HHS-RADV error rate calculation process; (2) specify that Super HCCs will be defined separately according to the age group model to which an enrollee is subject, except when the child and adult coefficient estimation groups have identical definitions; and (3) constrain to zero any failure rate group outlier with a negative failure rate, regardless of whether the outlier issuer has a negative or positive error rate.
- HHS Notice of Benefit and Payment Parameters for 2024 final rule (“2024 Payment Notice,” 88 FR 25740): On April 17, 2023, HHS published the 2024 Payment Notice to finalize the 2024 benefit year risk adjustment models HHS also finalized the repeal of the flexibility of prior participant States from requesting reductions of risk adjustment state transfers calculated by HHS under the state payment transfer formula in all state market risk pools for the 2025 benefit year and beyond. In addition, beginning with the 2023 benefit year, HHS finalized proposals to collect and extract a QSEHRA indicator as part of the risk adjustment data issuers of risk adjustment covered plans are required to make accessible to HHS on their EDGE servers in states where HHS operates the risk adjustment program. Similar to the race, ethnicity, and ICHRA indicator data elements finalized in the 2023 Payment Notice, HHS finalized the adoption of a transitional approach for collecting the QSEHRA indicator under which issuers will be required to populate this new QSEHRA indicator using data they already have or collect for the 2023 and 2024 benefit years. Then,

beginning with the 2025 benefit year, issuers will be required to populate the field using available sources and, in the absence of an existing source to populate the QSEHRA indicator for particular enrollees, issuers will be required to make a good faith effort to ensure collection of this data element. HHS also finalized a proposal to extract the plan identifier and rating area data elements from issuers' EDGE servers for benefit years prior to the 2021 benefit year. For HHS-RADV, HHS finalized changing the materiality threshold established under 45 CFR § 153.630(g)(2) for random and targeted sampling to 30,000 total billable member months (BMM) statewide. Beginning with the 2021 benefit year HHS-RADV, HHS also finalized no longer exempting exiting issuers from adjustments to risk scores and risk adjustment transfers if the exiting issuer is a negative error rate outlier. Therefore, HHS will apply HHS-RADV results to adjust the plan liability risk scores and state transfers of all issuers. Lastly, we finalized that the HHS-RADV Second Validation Audit (SVA) discrepancy window from 30 calendar days to 15 calendar days.

EDGE Data Collection

The transitional reinsurance program (for determining payments) and permanent risk adjustment (including the high-cost risk pool) program utilize the same data collection tool. For both programs, HHS collects issuers' data needed for program calculations via a distributed data collection (DDC) approach referred to as the EDGE server.

The reporting and data collection provisions described below apply to states and health plans both inside and outside of an Exchange because "risk adjustment covered plan" is defined at 45 CFR § 153.20 as "for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in § 146.145(b) of this subchapter, individual health insurance coverage described in § 148.220 of this subchapter, and any plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology" and a "reinsurance-eligible plan" is defined at 45 CFR § 153.20 as "for the purpose of the reinsurance program, any health insurance coverage offered in the individual market, except for grandfathered plans and health insurance coverage not required to submit reinsurance contributions under § 153.400(a)."

HHS continues to recalibrate the risk adjustment models and refine the HHS-developed risk adjustment methodology to improve the risk adjustment program. This supporting statement proposes to revise existing estimates based on the new data elements in six (6) areas: 1) ZIP code, 2) race, 3) ethnicity, 4) subsidy indicator, 5) ICHRA indicator, and 6) QSEHRA indicator to conform to statute and regulations.

B. Justification

1. Need and Legal Basis

Section 1341 of the ACA provides that each state must establish a transitional reinsurance program to help stabilize premiums for coverage in the individual market during the first three years of Exchange operation. Section 1343 provides for a program of risk adjustment for all non-grandfathered plans in the individual and small group market both inside and outside of the Exchange. Sections 1402 and 1412 of the ACA establish a program for reducing cost sharing for individuals with lower household income and Indians. Sections 1401 and 1411 of

the ACA provide for advance payments of the premium tax credit for low- and moderate-income enrollees in a qualified health plan (QHP) through an Exchange.

Section 1321(a) also provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, reinsurance, risk adjustment, and other components of title I of the ACA. These risk-spreading and insurance affordability programs, which will be implemented by HHS or states, are designed to mitigate adverse selection, to provide stability for health insurance issuers in the individual and small group markets as market reforms and Exchanges are implemented, and to make health insurance more affordable and accessible to millions of Americans who currently do not have affordable options available to them.

2. Information Users

The data collection and reporting requirements described below will enable states, the District of Columbia, and HHS to implement these programs, which will mitigate the impact of adverse selection in the individual and small group markets both inside and outside the Exchange.

3. Use of Information Technology

Information required by this collection will be submitted electronically. HHS staff will communicate with states and the District of Columbia using standardized reporting, e-mail, or telephone.

4. Duplication of Efforts

This information collection does not duplicate any other federal effort.

5. Small Businesses

This information collection will not have a significant impact on small businesses.

6. Less Frequent Collection

The anticipated flows of funds for these programs require the collection of information as indicated. A less frequent collection could result in cash flow difficulties for issuers and logistical difficulties for issuers and the entities operating premium stabilization programs.

7. Special Circumstances

In order for charges to be collected and payments to be made in a timely manner for the risk adjustment program, it is necessary to collect information according to timeframes established by the state or HHS on behalf of the state. For program integrity and to confirm accurate payments were made, it is necessary to collect information according to timeframes established by the state or HHS on behalf of the state.

8. Federal Register/Outside Consultation

A 60-day notice was published in the Federal Register on May 18, 2023 (88 FR 31759). One comment was received, and as a result of this comment, we provided more background information on the implementation timelines for the six new data elements, which were finalized in the 2023 Payment Notice and 2024 Payment Notice. A 30-day notice published in the Federal Register on August 17, 2023 (88 FR 56023).

9. Payments/Gifts to Respondents

No payments or gifts will be provided to respondents.

10. Confidentiality

We will maintain respondent privacy with respect to the information collected to the extent required by applicable law and HHS policies.

11. Sensitive Questions

There are no sensitive questions included in this information collection effort.

12. Burden Estimates (Hours & Wages)

Below is a summary of the information collection requirements set forth in the final rules and guidance cited above. Throughout this summary, the frequency of data collection is assumed to be the frequency discussed in these rules and guidance.

A number of assumptions are made regarding the wages of personnel needed to accomplish the proposed collection of information. Wage rates are based on the 2022 Employer Costs for Employee Compensation report by U.S. Bureau of Labor Statistics, available at <https://www.bls.gov/oes/tables.htm>, and represent a national average. Some states or employers may face higher or lower wage burdens. Wage rates estimates include a 100% fringe benefit estimate for all employees. We present an annualized estimate of the burden associated with these information collection requirements below.

I. Health Insurance Issuer Standards Related to the Transitional Reinsurance Program (§153.400-§153.420, §153.710, and §153.730)

Within Part 153, subpart E we discussed reporting requirements for health insurance issuers related to the transitional reinsurance program. As discussed above, this program ended in 2016 after most health insurance issuers and contributing entities provided HHS with data and made required reinsurance contributions and certain health insurance issuers provided HHS with data to receive reinsurance payments. However, we are still completing audits of issuers of reinsurance-eligible plans (i.e., those issuers who received reinsurance payments) and making refunds to contributing entities as applicable. Additionally, we need to collect similar data to the data HHS collected in accordance with §153.420(a) when HHS was making reinsurance payments from issuers operating in states that have requested HHS assistance to run a state-based reinsurance program (SRI) under an approved Section 1332 waiver. This data collection is described in conjunction with risk adjustment data submission requirements described in Part II below.

Audits and Compliance Reviews (§153.410(d))

HHS or its designee has the authority to audit and conduct compliance reviews of issuers of reinsurance-eligible plans to assess compliance with the requirements of subparts E and H of Part 153. For issuers of reinsurance-eligible plans, these provisions would result in a third-party disclosure requirement for issuers to prepare and compile the financial and programmatic information necessary to comply with the audit. Issuers being audited will also be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and

providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. If an audit results in a finding, issuers must also provide written corrective plans in the time and manner set forth by HHS. Unlike an audit, a compliance review may be targeted at a specific potential error and conducted on an ad hoc basis, which would allow HHS to address situations in which a systematic error or issue is identified during an audit and HHS suspects similarly situated issuers may have experienced the same error or issue but were not selected for audit in the year in question. While these requirements do impose burdens, data collection requirements associated with this audit program and compliance reviews are exempt from PRA requirements in accordance with 5 CFR 1320.4(a)(2) because this information would be collected during the conduct of an administrative action or investigation involving an agency against specific individuals or entities. As a result, although we describe the burdens associated with transitional reinsurance program audits and compliance reviews, we do not include estimates for burdens related to the transitional reinsurance program in the burden tables included at the end of this section.

We anticipate that compliance with reinsurance program audits will take 120 hours by a business operations specialist (at a rate of \$79.50 per hour), 40 hours by a computer systems analyst (at a rate of \$103.40 per hour), and 20 hours by a compliance officer (at a rate of \$74.02 per hour) per issuer per benefit year. The cost per issuer will be approximately \$15,156.40. There were 557 issuers participating in the reinsurance program for the 2015 benefit year and 496 issuers participating in the reinsurance program for the 2016 benefit year; however, HHS will only audit a small percentage of these issuers, roughly 30–60 issuers per benefit year. Depending on the number of issuers audited for each benefit year, the total cost to issuers being audited will be between \$454,692 and \$909,384, with an average annual cost of approximately \$682,038.

We anticipate that reinsurance program compliance reviews will take 30 hours by a business operations specialist (at a rate of \$79.50 per hour), 10 hours by a computer systems analyst (at a rate of \$103.40 per hour), and 5 hours by a compliance officer (at a rate of \$74.02 per hour) per issuer per benefit year. The cost per issuer will be approximately \$3,789.10. HHS only intends to conduct compliance reviews for no more than 15 issuers per benefit year and intends to focus these reviews on payments received by reinsurance-eligible plans under the program. The total annual cost to issuers undergoing compliance reviews will be approximately \$56,836.50.

Refunds of Reinsurance Contributions to Contributing Entities

HHS continues to refund contributing entities for overpayments of reinsurance contributions. As a result, we are retaining in this collection reinsurance data elements that issuers are required to provide to HHS in accordance with §153.400(b).

II. Health Insurance Issuer Standards for the Risk Adjustment Program (§153.610-§153.630 and §153.700-§153.730)

Within Part 153, subpart G, we described reporting requirements for health insurance issuers related to the risk adjustment program.

Distributed Data/EDGE Server and Reinsurance and Risk Adjustment Data Submission Requirements (§153.400, §153.420, §153.610, §153.700(a), §153.710, §153.720, and §153.730)

As described in §§ 153.400(b), 153.420(a), 153.610, and 153.710(a), health insurance issuers are required to maintain reinsurance and risk adjustment data in order for HHS to operate reinsurance and risk adjustment (including the high-cost risk pool) on behalf of a state. HHS has determined that issuers will need to maintain data elements identified in Appendix A. HHS employs a distributed data approach when running risk adjustment on behalf of a state and uses the same data for the purpose of determining the risk adjustment user fee for each issuer. In a previous update to the Supporting Statement 0938-1155, we included two new data elements in Appendix A, attached: regarding pharmacy claims, the number of days' supply (Days Supply) for prescription drugs and, regarding pharmacy and medical claims, a Claims In-Network and Out-of-Network Indicator, to improve our analysis of risk adjustment data.

We began collecting an indicator identifying out-of-network claims from issuers for enrollee-level EDGE data beginning with the 2018 benefit year. We previously established the use of enrollee-level EDGE data for risk adjustment recalibration and to inform the development of the AV calculator and methodology, in addition to using the data for calibrating other HHS individual and small group market programs, in the 2018 Payment Notice and in the 2020 Payment Notice. For the development of the AV calculator and estimating enrollees who reached the maximum annual limitation on cost sharing, HHS relies on identification of claims that were paid on an in-network basis.

Section 1302(c) of the ACA directs the Secretary of HHS to determine an annual premium adjustment percentage, a measure of premium growth that is used to set the maximum annual limitation on cost sharing. Under §156.130(c) that implements Section 1302(c) of the ACA, issuers cannot be required to include out-of-network claims toward the annual limitation on cost sharing. Therefore, to build the standard population for the AV calculator, HHS must be able to identify out-of-network claims. Because issuers already collect information on out-of-network claims, we estimate a business operations specialist requires 4 hours (at an hourly wage of \$79.50) to include this required indicator in the EDGE load, for an approximate cost of \$317.60 per issuer. For 650 issuers, we estimate this one-time requirement will incur 2,600 hours and cost \$206,440.

In this update to the Supporting Statement 0938-1155, we add the collection and extraction of six new EDGE data elements in Appendix A, including: 1) ZIP code, 2) race, 3) ethnicity, 4) subsidy indicator, 5) ICHRA Indicator, and, 6) QSEHRA Indicator beginning with benefit year 2023.^{2,3} As overviewed in the Proposed 2023 Notice of Benefit and Payment Parameters,⁴ collecting and extracting these new and current data elements will allow HHS to further assess and analyze actuarial risk and risk patterns in the individual, small group, and merged markets, and determine if, based on future analysis, any refinements to the HHS risk adjustment methodology, the AV Calculator, or other HHS individual or small group (including merged) market programs should be proposed through notice-and-comment rulemaking.

This supporting statement includes estimates specific to the new data elements and the incremental information collection associated with the requirements of the new data collection. As such, although the new data collection requires that issuers transform and

² The first five (5) new elements were finalized in the 2023 Notice of Benefit and Payment Parameters and are also referred to as the “five new data elements” throughout the Supporting Statement 0938-1155. 87 FR 27208 at 27241-27243.

³ The QSEHRA Indicator was finalized in the 2024 Notice of Benefit and Payment Parameters. 88 FR 25740 at 25781.

⁴ 87 FR 584 at 627-632.

submit additional data elements, it does not require changes to the process or distributed data collection approach currently used by an issuer to submit and make risk adjustment data accessible to HHS. We estimate approximately \$3,623.04 in total one-time labor costs (reflecting 6 hours of work per data element by a management analyst at an average hourly rate of \$100.64 per hour), including approximately \$3,019.20 for each issuer for the five new data elements finalized in the 2023 Payment Notice and an additional \$603.84 for the collection of the QSEHRA Indicator finalized in the 2024 Payment Notice. The cumulative one-time cost to update issuers' file creation process is \$2,354,976.00 for 650 issuers (23,400 total hours for all issuers). This includes \$1,962,480.00 for 650 issuers (19,500 total hours for all issuers) related to the collection of the five new elements, and an additional \$392,496.00 for 650 issuers (3,900 total hours for all issuers) for the QSEHRA Indicator.

In addition, we estimate approximately \$603.84 in total labor costs per year (reflecting 1 hour of work per data element by a management analyst at an average hourly rate of \$96.66 per hour), including approximately \$503.2 for each issuer for the five new data elements finalized in the 2023 Payment Notice and an additional \$100.64 for the collection of the QSEHRA Indicator finalized in the 2024 Payment Notice. The cumulative additional annual cost estimate as a result of the collection of five new data elements is \$327,106 for 650 issuers (3,250 total hours per year for all issuers), and an additional \$65,416.00 for 650 issuers (650 total hours per year for all issuers) for the QSEHRA Indicator. This totals a cumulative additional annual cost estimate of \$392,496.00.

Under §153.610(f), we established a user fee to support HHS operation of the risk adjustment program in states that elect not to operate their own risk adjustment program. This per capita monthly fee is charged to issuers of risk adjustment covered plans based on enrollment data provided to HHS in the distributed data environment. HHS calculates risk adjustment user fees, and issuers remit the assessed user fee once annually, in August of the year following the benefit year, in connection with processing payments and charges for risk adjustment. We estimate that approximately 650 issuers will be required to pay risk adjustment user fees, and the additional cost associated with this requirement is the time and effort for an issuer to remit fees. Because HHS utilizes existing data collection and payments and charges processing, we do not anticipate that this provision will alter the collection cost.

Under a distributed data approach, the required data is accessed and stored separately from other issuer data pursuant to formats specified by HHS. In §153.700(a), we require that an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a state where HHS is operating the risk adjustment or reinsurance program on behalf of the state, as applicable, to provide HHS access to its data through the dedicated data environment as specified by HHS. We estimate that this data submission requirement will affect approximately 650 issuers, and will cost each issuer approximately \$579,686.40 in total labor costs. This cost estimate reflects the wages of 3 full-time equivalent employees (5,760 hours per year) at an average hourly rate of \$100.64 per hour for a management analyst. Issuers have already established EDGE servers to process claims, so we are reducing the capital cost in section 13 below to a total of \$30,000 for all issuers per year to account for the possibility that only two new EDGE servers would need to be set up annually. For risk adjustment (including high-cost risk pool), we anticipate that 650 issuers will process approximately 9 billion claims and enrollment files annually (approximately 13.8 million claims and enrollment

files per issuer). Therefore, we estimate an aggregate annual burden, including labor and capital costs (as described in section 13 below), of \$396,296,160 for all issuers as a result of these requirements. To ensure timely and accurate risk adjustment transfers, HHS asks issuers to make complete, current enrollment and claims files accessible through its dedicated distributed data environments no less frequently than quarterly.

HHS has issued guidance giving issuers the option of uploading supplemental diagnoses to their EDGE servers in addition to the other enrollee, claims and medical data elements that are required for the risk adjustment program (see Appendix A). If an issuer chooses to submit supplemental diagnosis information, HHS has determined that issuers will need to maintain the data elements identified in Appendix A. In this collection, we rename 10 data elements in the Supplemental Diagnoses section of Appendix A to accurately reflect existing data specifications for this optional submission. The burden associated with this requirement is the additional effort for an issuer to gather and submit supplemental diagnoses to HHS.

Based on HHS experience from 2019 and 2020 benefit years, we estimate that approximately 85 to 100 percent of the 650 issuers of risk adjustment covered plans will submit this information for 10 percent of their enrollees. Because we estimate that issuers will only submit supplemental diagnoses for 10 percent of their enrollees, we believe that the time and effort associated with this process will be approximately 10 percent of the time and effort associated with uploading information to the distributed data environment. As an upper level estimate, we anticipate that all 650 issuers will process approximately 900 million supplemental diagnoses claims or about 1.4 million claims per issuer. We estimate that it will take 3 full-time equivalent employees (at an average hourly wage rate of \$100.64 for a management analyst) approximately 576 hours per year per issuer to submit supplemental diagnoses to HHS. For 650 issuers, we estimate an aggregate burden of 374,400 hours and \$37,679,616 associated with this optional data submission.

As described in §153.720(a), an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a state in which HHS operates risk adjustment or reinsurance, as applicable, must establish a unique masked enrollee identification number for each enrollee, in accordance with HHS-defined requirements, and maintain the same masked enrollee identification number for an enrollee across enrollments or plans within the issuer, within the state, during a benefit year. Under §153.720(b), an issuer of a risk adjustment covered plan or reinsurance-eligible plan in a state in which HHS is operating the risk adjustment or reinsurance program, as applicable, may not include an enrollee's personally identifiable information in the masked enrollee identification number or use the same masked enrollee identification number for different enrollees enrolled with the issuer. The term "personally identifiable information" is a broadly used term across federal agencies, and has been defined in the Office of Management and Budget (OMB) Memorandum M-07-16 (May 22, 2007).⁵

We estimate that 650 issuers will be affected by the requirement to maintain a masked enrollee identification number for each enrollee. The cost of setting up a masked identity for each enrollee would be the time and effort required to assign an identification number to each enrollee and remove other identifying factors from the enrollee's profile or claims information as submitted to HHS. We estimate it would cost each issuer approximately

⁵ Available at: https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2007/m07-16.pdf.

\$301.92 per year, based on three hours of work by a management analyst at \$100.64 per hour. Therefore, we estimate an aggregate total annual burden of 1,950 hours at an estimated cost of \$196,248 for all issuers to maintain a masked enrollee identification number.

Under § 153.710(d) an issuer must either confirm to HHS that the information in the final dedicated distributed data environment report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with § 153.700(a) for the benefit year specified in the report, or describe to HHS any inaccuracy it identifies in the final dedicated distributed data environment report within 15 calendar days of the date of the report.

We estimate that 650 issuers of risk adjustment covered plans will be subject to this requirement, and that issuers will compare enrollee condition codes with risk scores and analyze claims costs to confirm information in the final dedicated distributed data environment reports. On average, in any given benefit year, we estimate that it will take a business operations specialist (at an hourly wage rate of \$79.50) approximately 6 hours to review and respond to the final dedicated distributed data environment report. Therefore, we estimate an aggregate burden of 3,900 hours and \$310,050 for 650 issuers as a result of this requirement.

High-Cost Risk Pool Adjustment (§153.320)

Beginning with the 2018 benefit year, HHS implemented a high-cost risk pool adjustment as part of the risk adjustment program. Beginning with the 2018 benefit year, HHS reimbursed issuers for a percentage of claims amounts above a certain threshold for high-cost enrollees, calculated using EDGE server data and funded by a charge on all issuers of risk adjustment covered plans equal to a percent of premium, by market nationally.

All issuers of risk adjustment covered plans are subject to this high-cost risk pool adjustment. Since HHS will assess charges to all issuers of risk adjustment covered plans to fund the high-cost risk pool adjustment, issuers will be required to submit premium and enrollment data to HHS beginning for the 2018 benefit year, so that HHS can calculate the national high-cost risk pool charge.

Issuers that are the sole issuer in a risk pool will also be required to submit enrollment and premium data, even if they choose not to submit data to the EDGE server due to the lack of a risk adjustment transfer based on plan liability risk scores with another issuer in their risk pool. The burden associated with a submission by an issuer in a single issuer risk pool is included in the burden for the risk adjustment program data submission requirements, as previously described.

State Flexibility for Risk Adjustment (§153.320)

In the 2019 Payment Notice (83 FR 16930), we finalized a policy to allow State regulators to request a reduction, beginning for the 2020 benefit year, to risk adjustment transfers in the individual, small group or merged markets. Any State requesting this reduction must submit its request with the supporting evidence and analysis to HHS identifying the State-specific factors that warrant the adjustment to more precisely account for the differences in actuarial risk in the State's individual, small group or merged market. Additionally, the State must submit supporting evidence and analysis demonstrating the reduction percentage requested is appropriate. This evidence and analysis justifying the percentage

requested must either demonstrate the set of factors and the percentage by which those factors warrant an adjustment to more precisely account for the differences in actuarial risk in the State's individual, small group or merged market compared to the national norm, or it must demonstrate the requested reduction in risk adjustment payments would be so small for issuers who would receive risk adjustment payments, that the reduction would have a de minimis effect on the necessary premium increase to cover the affected issuer or issuers' reduced payments. States are required to submit the requests with the supporting evidence and analysis by August 1st, 2 calendar years prior to the beginning of the applicable benefit year.

In the 2023 Payment Notice, we repealed the ability, other than for "prior participants," to request a reduction in risk adjustment state transfers starting with the 2024 benefit year. "Prior participant" is defined as a state that submitted a state reduction request in the state's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool in the 2020, 2021, 2022, or 2023 benefit year. Beginning with the 2024 benefit year, only prior participants can make such requests and the requests will only be reviewed and approved under the de minimis threshold framework and criteria as described above. Then, in the 2024 Payment Notice, we finalized the repeal of prior participants States to request a reduction in risk adjustment transfers beginning with the 2025 benefit year, which means that no state will be able to request this state flexibility in the future. Therefore, the update to this supporting statement removes this previous burden estimate.

Audits and Compliance Reviews of Issuers of Risk Adjustment Covered Plans (including high-cost risk pool) (§153.620(c))

In the 2022 Payment Notice (86 FR 24140), we clarified policies around the auditing of issuers of risk adjustment covered plans (including to ensure the proper payment of high-cost risk pool payments) and confirm compliance with applicable requirements in subparts G and H of part 153. Issuers being audited under the risk adjustment program (including high-cost risk pool) will be required to comply with audit requirements including participating in entrance and exit conferences, submitting complete and accurate data to HHS in a timely manner, and providing responses to additional requests for information from HHS and to preliminary audit reports in a timely manner. If an audit results in a finding, issuers must also provide written corrective plans in the time and manner set forth by HHS. Unlike an audit, a compliance review may be targeted at a specific potential error and conducted on an ad hoc basis, which would allow HHS to address situations in which a systematic error or issue is identified during an audit and HHS suspects similarly situated issuers may have experienced the same error or issue but were not selected for audit in the year in question. While these requirements do impose burdens, data collection requirements associated with the risk adjustment program (including high-cost risk pool) audit program are exempt from PRA requirements in accordance with 5 CFR 1320.4(a)(2) because this information would be collected during the conduct of an administrative action or investigation involving an agency against specific individuals or entities. As a result, although we describe the burdens associated with these audits, we do not include estimates for burdens related to these audits in the burden tables included at the end of this section.

We anticipate that compliance with risk adjustment program (including high-cost risk pool) audits will take 120 hours by a business operations specialist (at a rate of \$79.50 per hour), 40 hours by a computer systems analyst (at a rate of \$103.40 per hour), and 20 hours by a compliance officer (at a rate of \$74.02 per hour) per issuer per benefit year. The cost per

issuer will be approximately \$15,156.40. While the number of issuers participating in the risk adjustment program varies per benefit year, we only intend to audit roughly 30–60 issuers per benefit year, and intends to focus these audits on payments under the high-cost risk pool. Depending on the number of issuers audited each year, the total cost to issuers being audited will be between \$454,692 and \$909,384, with an average annual cost of approximately \$682,038.

We anticipate that risk adjustment program (including high-cost risk pool) compliance reviews will take 30 hours by a business operations specialist (at a rate of \$79.50 per hour), 10 hours by a computer systems analyst (at a rate of \$103.40 per hour), and 5 hours by a compliance officer (at a rate of \$74.20 per hour) per issuer per benefit year. The cost per issuer will be approximately \$3,789.10. While the number of issuers participating in the risk adjustment program varies per benefit year, we only intend to conduct compliance reviews for no more than 15 issuers per benefit year and intends to focus these reviews on payments under the high-cost risk pool. The total annual cost to issuers undergoing compliance reviews will be approximately \$56,836.50.

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

As described in §153.630, health insurance issuers must comply with risk adjustment data validation activities as specified by HHS or states. The burden associated with this requirement is the issuer's time and effort to provide HHS with source claims, medical records, and enrollment information to validate enrollee demographic, enrollment and health status information for initial and second validation audits for a sample of enrollees, and the issuer's cost to employ an independent auditor to perform the initial validation audit on a statistically valid sample of enrollees. While these requirements do impose burdens, data collection requirements associated with HHS-RADV are exempt from PRA requirements in accordance with 5 CFR 1320.4(a)(2) because this information would be collected during the conduct of an administrative action or investigation involving an agency against specific individuals or entities. As a result, although we describe the burdens associated with HHS-RADV, we do not include estimates for these burdens in the burden tables included at the end of this section.

In the 2015 Payment Notice (79 FR 13743), we revised the audit sample size downward so that each issuer's audit sample consists of approximately 200 enrollees. As finalized in the 2020 Payment Notice (84 FR 17454), we use the Neyman allocation methodology beginning with benefit year 2019 HHS-RADV to determine the appropriate size of enrollee strata within each issuer's HHS-RADV sample. Based on benefit years 2019 and 2020 HHS-RADV, each issuer's audit sample consists of approximately 172 enrollees with HCCs. As finalized in the 2019 Payment Notice, beginning with benefit year 2017 HHS-RADV, issuers with 500 or fewer billable member months statewide are excluded from performing an initial validation audit. As finalized in the 2020 Payment Notice, issuers in liquidation who met certain conditions, sole market risk pool issuers, and small group market issuers with off- calendar year coverage who exit the market but have only carry-over coverage that ends in the next benefit year would also be exempt from HHS-RADV. In addition, as established in the 2019 Payment Notice (83 FR 16930), issuers below a materiality threshold of total annual statewide premiums of less than \$15 million and not otherwise exempt from HHS-RADV will be subject to random and targeted participation in HHS-RADV, being selected to participate at a frequency of approximately once every three years, starting with 2018 benefit year HHS-RADV.

In the 2024 Payment Notice, we finalized modifying the materiality threshold for participation in HHS-RADV from \$15 million in total annual statewide premiums to 30,000 total statewide BMM. Under this revised definition of materiality, HHS conducts random and targeted sampling for issuers below the materiality threshold such that issuers at or below the 30,000 total statewide BMM threshold and not otherwise exempt from HHS-RADV are subject to participation in HHS-RADV approximately once every 3 years. Based on HHS-RADV for benefit years 2018–2021, we estimate that one-third of the approximately 200 issuers with less than 30,000 total statewide BMM will be subject to an initial validation audit each year. In our analysis of historical data on issuers of risk adjustment covered plans, we found that the pool of issuers falling below a 30,000 BMM statewide threshold does not differ significantly from the pool of issuers falling below a \$15 million total annual statewide premium threshold. Therefore, between issuers with greater than 30,000 total statewide BMM, who participate annually in HHS-RADV, and issuers with less than 30,000 total statewide BMM, who participate in HHS-RADV approximately once every three years, we anticipate an upper estimate of 650 issuers would participate in HHS-RADV for any given benefit year.

Under §153.630(b)(1), an issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an IVA of a sample of its risk adjustment data selected by HHS. Under this provision, the issuer must provide HHS with the identity of the initial validation auditor, and attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), in a timeframe and manner specified by HHS. The additional burden associated with this reporting requirement is the time and effort necessary to report the auditor's identity to HHS. Additionally, an issuer must review and attest to its IVA sample or qualify its attestation by submitting a sampling discrepancy. An issuer must also review the IVA findings submitted to the audit tool and complete a signoff action within the audit tool to indicate it concurs with the IVA findings and that its IVA submission is complete. We estimate it will take an operations manager (at an hourly wage rate of \$118.14) approximately 30 minutes to complete these reporting requirements. For each issuer, we anticipate the burden would be approximately 30 minutes of work at a cost of \$59.07. Therefore, for the upper estimate of 650 issuers required to submit reports for HHS-RADV for any given benefit year, the aggregate burden associated with this reporting requirement is 325 hours, at an approximate cost of \$38,395.50.

As part of conducting the IVA, the issuer must review the IVA sample and determine which enrollees will require medical records to validate their HCCs. From the enrollees' claims data, issuers need to determine the source of the claim, for example, the provider submitting the claim and dates of service. The issuer must then request these medical records from various providers. Issuers may request and collect these medical records themselves, include it in their contract with the initial validation auditor, or hire a third party. After requests for medical records are made, tracking of the responses to these requests and additional follow-up is required. In addition, the issuer (or other entity if the issuer has contracted this work to another party), will review the received medical records to ensure they are legible, complete, and include the necessary signatures. If the medical record is not signed, a signature attestation may need to be requested. Based on past experience, approximately 172 enrollees in an issuer sample will require medical records to validate HCCs, with approximately five medical record requests per enrollee

(approximately 860 medical record requests per issuer). We estimate it will take a business operations specialist (at an hourly wage rate of \$79.50) approximately one hour to complete, review, and conduct follow-up on each medical record request (20 minutes each to complete each medical record request, review the response to each medical record request, and to conduct further follow-up on each medical record request). For each issuer, we anticipate the burden would be approximately 860 hours at a cost of \$68,370. For an estimated 650 issuers required to submit samples for HHS-RADV for any given benefit year, we anticipate that the aggregate burden of completing medical record reviews will be approximately 559,000 hours and \$44,440,500.

Based on a review of EDGE data for 2017–2019 benefit years, we have determined that for enrollees with HCCs, the average number of HCCs to be reviewed by a certified medical coder per enrollee is approximately three HCCs. Additionally, based on HHS audit experience, we estimate that it may cost approximately \$423.63 (\$62.76 per hour for 6.75 hours on average) for a certified medical coder to review the medical record documentation for one enrollee with roughly three HCCs. For 172 enrollees with HCCs in an issuer sample, the total cost to each issuer would be \$72,864.36 (for 1,161 hours). In some cases, a secondary review by a senior certified medical coder (at an hourly wage rate of \$62.76 per hour) will be needed to re-review approximately one-third of the medical record documentation required during the first review. Thus, a senior certified medical coder would need to review medical documentation for the equivalent of approximately 57 enrollees with HCCs in an issuer sample. We estimate that the total cost to each issuer would be approximately \$24,146.91 (\$62.76 per hour for 6.75 hours per enrollee). For this review and secondary review, the total cost to each issuer would be approximately \$97,011.27 (1,545.75 total hours). In addition, we expect that it may cost approximately \$20.92 per enrollee (\$62.76 per hour for 20 minutes) to validate demographic information for 50 enrollees in each audit sample totaling \$1,046.00 per issuer.

In addition, beginning with 2018 HHS-RADV, an initial validation audit entity is required to conduct a prescription drug category (RXC) review. The audit entity must review RXCs for all adult enrollees in the audit sample with at least one RXC. Based on the most recent HHS audit experience, we update our estimate in this collection to assume that an initial validation audit will be performed on approximately 50 RXCs per issuer, rather than the previously estimated 71 RXCs per issuer. We estimate that this validation would cost approximately \$20.92 per RXC (\$62.76 per hour for 20 minutes), totaling \$1,046.00 per issuer. In addition, for each issuer, we expect it would require a compliance officer working 40 hours at \$74.02 per hour, and 2 operations managers working a total of 80 hours at \$118.14 per hour to make available to external medical coders associated with the initial validation audit entity claims documents for review of demographic information and RXC review (120 hours at a combined cost of \$12,412).

For each issuer submitting audit findings for HHS-RADV in a given benefit year, the total burden for reporting, coding, and administration would be approximately 2,559.58 hours at a cost of \$179,944.34 per issuer. For an estimated 650 issuers required to submit audit findings for HHS-RADV for any given benefit year, we anticipate that the aggregate burden of conducting IVAs will be approximately 1,663,729.17 hours and \$116,963,821.00. We note that this is the upper bound burden, and fewer issuers will be

subject to this requirement in future years.⁶

Under §153.630(b)(8), the initial validation auditor is required to attest to HHS that they performed inter-rater reliability (IRR) among their primary coder reviewers using HHS standards or IVA standards approved by HHS until a 95% consistency threshold is achieved. A senior coder must review the medical records of a primary coder that does not meet the 95% consistency threshold. Those findings are documented as the final results on the IVA Entity Audit Results Submission XML. Establishing IRR is a standard practice within the industry, and we therefore believe costs associated with this review are already accounted for in the above estimates.

To reiterate, while these HHS-RADV requirements do impose burdens, data collection requirements associated with HHS-RADV are exempt from PRA requirements in accordance with 5 CFR 1320.4(a)(2) because this information would be collected during the conduct of an administrative action or investigation involving an agency against specific individuals or entities. As a result, although we describe the burdens associated with HHS-RADV, we do not include estimates for these burdens in the burden tables included at the end of this section.

Mental and behavioral health records §153.630

For risk adjustment data validation, HHS requires issuers to document mental and behavioral health records included in audit sampling. Without the necessary mental and behavioral health information for each sample, the diagnosis code for an applicable enrollee cannot be validated and, therefore, it would be rejected during risk adjustment data validation.

Because providers may be prevented under some state privacy laws from furnishing a full mental health or behavioral health record, we provided issuers in the 2019 Payment Notice at §153.630(b)(6) an additional avenue to achieve compliance with data validation requirements by permitting abbreviated mental or behavioral health assessments for risk adjustment data validation in the event that a provider is subject to state privacy laws that prevent the provider from providing HHS with a complete mental or behavioral health record. To submit a mental or behavioral health assessment, a provider would be required to attest that relevant state privacy laws prevent him or her from providing the entire mental or behavioral health record.

HHS expects that this provision may affect 10 percent of issuers or approximately 65 issuers in states with stricter privacy laws on medical records. Based on data from 2017 and 2018 initial validation audits, we estimate that approximately 10 enrollees in any initial validation audit sample of 200 enrollees could be affected by the stricter privacy laws. Providers routinely prepare assessments to validate diagnoses, therefore, we believe the additional burden is the time it would take to seek patient consent to provide the assessment, in states that require such permission, and for a provider to prepare an abbreviated assessment for each medical record and to attest that relevant state privacy laws prohibit him or her from providing the entire mental or behavioral health record.

We estimate it would take a medical records technician (at an hourly wage of \$49.12) 15

⁶ As a result of the policies in the 2019 and 2020 Payment Notices that established exemptions from HHS-RADV for certain issuers, fewer than 650 issuers each year will be subject to this requirement in future years.

minutes to obtain consent from each patient, or approximately 2.5 burden hours at an estimated cost of \$122.80 per issuer. In addition, we estimate a qualified licensed provider (at an hourly wage of \$237.84) would need 45 minutes to prepare an abbreviated assessment and sign an attestation, for a total of \$178.38 per enrollee, or \$1,783.80 per issuer. Therefore, for 10 patients, the total burden per issuer for the provision to obtain consent from each patient and prepare an abbreviated assessment and signed attestation would be 10 hours and approximately \$1,906.60. The aggregated burden for the estimated 65 affected issuers would be 650 hours and approximately \$123,929.

Table 1 - Burden Estimates for Risk Adjustment Data Collection and Data Validation

Information Collection Requirement	Type of Respondent	Frequency and Duration	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Claim In-Network or Out-of-Network Indicator	Issuer	Annually	650	1	4	2,600
Risk adjustment distributed data collection	Issuer	Annually	650	1	5,760	3,744,000
Supplemental diagnoses	Issuer	Annually	650	1	576	374,400
Masked enrollee information	Issuer	Annually	650	1	3	1,950
Respond to the final distributed data report	Issuer	Annually	650	1	6	3,900
Six new EDGE data elements ⁷	Issuer	One-time	650	1	36	23,400
Six new EDGE data elements ⁸	Issuer	Annually	650	1	6	3,900
Total						4,154,150

Table 2 - Burden Estimates for Risk Adjustment Data Collection and Data Validation by Labor Category

Type of Respondent	Hourly Labor Cost of Reporting (\$) (wage includes 100% fringe benefits rate)	Number of Respondents	Total Burden Hours	Average Labor Cost per Response	Total Labor Costs (All Respondents)
Business Operations Specialist (BLS 13-1199)	\$79.50	1,300	6,500	\$397.5	\$516,750
Management Analyst (BLS 12-1111)	\$100.64	1,950	4,147,650	\$214,061.28	\$417,419,496
Total			4,154,150		\$417,936,066

⁷ See supra notes 3 and 4.

⁸ See supra notes 3 and 4.

III. Appeals for Premium Stabilization Programs (§156.1220)

Under § 156.1220 and associated guidance, issuers may use an administrative appeal process to address unresolved discrepancies for the premium stabilization programs, as well as any assessment under §153.740(b) of a default risk adjustment charge. While these requirements do impose burdens, data collection requirements associated with appeals are exempt from PRA requirements in accordance with 5 CFR 1320.4(a)(2) because this information would be collected during the conduct of an administrative action or investigation involving an agency against specific individuals or entities. As a result, although we describe the burdens associated with the appeals process, we do not include estimates for these burdens in any burden table.

Under § 156.1220(a), which includes programs that expired in 2016, an issuer may file a request for reconsideration to contest a processing error by HHS (i.e., an incorrect loading or use of data), an incorrect application of the relevant methodology, or a mathematical error for: (1) the amount of risk adjustment payments or charges (including high-cost risk pool) for a benefit year, including an assessment of risk adjustment user fees; (2) the amount of reinsurance payments for a benefit year; (3) the amount of a risk adjustment default charge for a benefit year; (4) the amount of risk corridors payments or charges for a benefit year; (5) the findings of a second validation audit as a result of risk adjustment data validation (if applicable) with respect to risk adjustment data for the 2016 benefit year and beyond;⁹ or (6) the calculation of a risk score error rate as a result of risk adjustment data validation with respect to risk adjustment data for the 2016 benefit year and beyond.¹⁰

While the hours involved in a request for reconsideration may vary, for the purpose of this burden estimate we estimate that it will take a business operations specialist 4 hours (at an hourly wage rate of \$79.50) to make the comparison and submit a discrepancy report, if applicable, and a request for reconsideration to HHS. We estimate that less than 11 issuers that may be eligible for reinsurance payments, risk adjustment payments or charges (including high-cost risk pool payments and charges, HHS-RADV adjustments to risk adjustment transfers, any assessment of risk adjustment user fees or a default risk adjustment charge) will submit a request for reconsideration for any of these programs for a total aggregate burden related to appeals of approximately 44 hours and an estimated cost of \$3,498.

Additionally, under §156.1220(b), an issuer dissatisfied with the reconsideration decision regarding: (1) risk adjustment payments and charges, including an assessment of risk adjustment user fees, (2) reinsurance payments, (3) default risk adjustment charges, (4) risk corridors payments or charges, (5) second validation audit findings (as applicable), or (6) risk score error rate calculations, provided under paragraph (a) of §156.1220, is entitled to an informal hearing before a CMS hearing officer, if a request is made in writing within 30 calendar days of the date the issuer receives the reconsideration decision. Further review is available from the CMS Administrator. However, because we believe these processes will occur extremely infrequently, we are not estimating the burden related to this requirement.

⁹ The 2016 benefit year of HHS-RADV was a pilot year. See HHS-RADV Amendments Rule, 85 FR at 76980. As such, this provision applies to the 2017 benefit year of HHS-RADV and beyond.

¹⁰ 85 FR at 76980.

13. Capital Costs

Regardless of the data format and specifications for the risk adjustment program, issuers will need to extract and, for purposes of audit, store the necessary data elements separately from data used during the normal course of business. We now estimate that in any given year, two new issuers will need to establish an EDGE server and that the one-time cost will be on average \$15,000. Therefore, we estimate a total capital burden for all issuers subject to this requirement of \$30,000. This estimate does not include the labor costs associated with data and server maintenance, which are estimated separately.

14. Cost to Federal Government

We estimate the annual cost to the federal government annually in each applicable benefit year’s Payment Notice. For each of the 2023 and 2024 benefit years, we estimated that the total cost for HHS to operate the risk adjustment program (including HHS-RADV and high-cost risk pool) on behalf of states will be approximately \$60 million. The calculations for CCIIO employees’ hourly salary were obtained from the OPM website <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>.

Table 3 – Administrative Burden Costs for the Federal Government Associated with the Risk Adjustment and Reinsurance Programs

Task	Estimated Cost
Risk Adjustment and Reinsurance Programs (PPFMG Staff)	
33 GS-12-5: x \$102.65 FTE	\$7,045,896
Cost of Contracts for HHS-operated Reinsurance and Risk Adjustment	\$60,000,000
Total Costs to Government	\$67,045,896

15. Explanation for Program Changes or Adjustments

This revision includes a slight increase (+27,300) in burden from approximately 4,126,850 hours to 4,154,150 hours, due to the additional collection and extraction of six (6) new EDGE data elements in for the Risk Adjustment and Reinsurance data collection (Appendix A).

16. Publication/Tabulation Dates

The data collection will be published for this revision.

17. Expiration Date

The expiration date and OMB control will be displayed on each instrument (first page, top right corner).