



***Affordable Care Act (ACA) HHS-Operated Risk Adjustment Data Validation
(RADV) Process White Paper
June 22, 2013***

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Introduction

The Patient Protection and Affordable Care Act (Pub. L. 111-148), herein referred to as the Affordable Care Act (ACA) establishes three programs to help stabilize premiums in the insurance market, with the goal of eliminating the potential effects of adverse selection. The programs include transitional reinsurance, temporary risk corridors, and permanent risk adjustment. This white paper focuses on the data validation process when the Department of Health and Human Services (HHS) is operating a risk adjustment program on behalf of a state (referred to as the “HHS-operated risk adjustment program”). Standards for states, or HHS on behalf of states, to implement a risk adjustment data validation (RADV) process are provided in the Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment Final Rule (45 C.F.R. Part 153), published at <http://www.gpo.gov/fdsys/pkg/FR-2012-03-23/pdf/2012-6594.pdf> on March 23, 2012. This rule is herein referred to as the Premium Stabilization final rule. The HHS Notice of Benefit and Payment Parameters for 2014 Final Rule (herein referred to as the 2014 Final Payment Notice) also provided additional standards for issuers when HHS is operating risk adjustment on behalf of a state, published at <http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf> on March 11, 2013.

Overview of the HHS-Operated Risk Adjustment Program

The risk adjustment program transfers funds from health insurance plans that enroll the lower risk individuals to plans that enroll the higher risk individuals. The goal is to eliminate premium differences among plans based solely on favorable or unfavorable risk selection in the individual and small group markets both inside and outside of the Marketplace. As a result of payments and charges applied to non-grandfathered individual and small group plans inside and outside of the Marketplace, the risk adjustment program levels the playing field and mitigates the potential for higher premiums due to adverse selection.

The 2014 Final Payment Notice provides the risk adjustment methodology that will apply to all issuers in 2014 in states where HHS is operating the risk adjustment program on behalf of the state. The methodology defines key principles by which the risk adjustment model was developed and will be applied. Specifically, the risk adjustment methodology uses a concurrent model containing individual level demographics and disease profiles to predict plan liability for services provided to enrollees in a given year. The concurrent model is based on demographics (age and sex) and diagnoses (ICD-9-CM and ICD-10-CM codes); age group (infant, child, or adult); and plan metal level (bronze, silver, gold, platinum, and catastrophic). The enrollee age/sex categories are mapped using the age and sex demographics of each enrollee, and enrollee risk adjustment diagnoses (or relevant diagnoses) are mapped to hierarchical condition categories (HCCs). These categories are assigned relevant risk factors that are additive to compute the enrollee's risk score. Individual risk scores are used to calculate a plan's average actuarial risk for a risk adjustment covered plan. The calculation of a plan's average actuarial risk also includes adjustments for rating variations (i.e., age and geography) and the specification of the risk pool from which average actuarial risk is to be calculated and applies to payment transfers.

Under the risk adjustment program each issuer in states where HHS is operating the program will to set up a dedicated secure server (referred to as "edge server") on which the issuer must provide masked enrollee demographics and claims and encounter diagnosis-level data in HHS-specified formats as provided in the Edge Server Interface Control Document. The most recent information about risk adjustment data collection format requirements and specifications can be found at www.regtap.info under "Distributed Data Collection". HHS will continue to provide data collection resources as they become available.

HHS will execute software on each issuer's edge server to calculate enrollee level risk scores and average plan liability risk scores (or plan average risk scores). This information will then be used to calculate payment transfers for all issuers of risk adjustment eligible

plans within a state market. A full description of the payment transfer formula including other rating and adjustment parameters is included in the 2014 Final Payment Notice.

Purpose of ACA HHS-Operated Risk Adjustment Data Validation

The purpose of data validation for risk adjustment is to promote confidence in the budget neutral payment transfer methodology by ensuring the integrity and quality of data provided from issuers operating in state markets under the HHS-operated risk adjustment program. 45 C.F.R § 153.350 requires states or HHS on behalf of states to validate a statistically valid sample of data for all issuers that submit data for risk adjustment every year, and provide for an appeals process. The 2014 Final Payment Notice provides requirements for an HHS-established data validation process and discusses the process to make adjustments to payments to issuers to reflect the accurate health risk status of their enrollee populations.

Purpose of White Paper

Although the Premium Stabilization final rule and 2014 Final Payment Notice direct states or HHS on behalf of states to conduct data validation for the risk adjustment program, the data validation methodology and process will be developed in sub-regulatory technical guidance and in consultation with stakeholders, especially in the first year of the program. The purpose of this white paper is to initiate stakeholder engagement, stimulate thoughts and discussion on the ACA HHS-operated RADV process, and to provide stakeholders the opportunity to submit comments to HHS. It is the first phase in HHS' engagement with stakeholders prior to updating or clarifying policies for the HHS-operated risk adjustment program. We will also organize stakeholder engagement meetings to discuss HHS' considerations in this white paper.

We acknowledge the importance of engaging stakeholders as well as providing technical assistance to states and issuers in order to facilitate appropriate and efficient

implementation of the ACA HHS-operated RADV. We also recognize that regular discussions with and assistance to states and health insurance issuers is important for a smooth implementation of the risk adjustment program. HHS seeks feedback on the questions raised throughout this paper. The comments and information obtained in response to the white paper and stakeholder engagement meeting may be used by HHS to inform future policy making for the risk adjustment data validation process.

In this paper, we provide background on the policy for the ACA HHS-operated RADV and continue with a discussion of each component of the ACA HHS-operated RADV process, posing questions for stakeholder consideration where appropriate. In particular, we seek stakeholder input on the development of the data validation audit standards, initial validation audit (IVA) process, options for applying the second validation audit (SVA) findings for error estimation, and an appeals process.

This white paper is outlined as follows:

- **Data Validation General Audit Standards.** This section describes common review elements of the initial and second validation audits. The discussion focuses on standards for source data and documentation.
- **Sampling.** This section provides a description of the sampling approach that HHS will use for the 2014 benefit year.
- **IVA Entity Requirements and Process Expectations.** This section provides a description of the standards for issuer selection and approval of an IVA entity. The discussion also includes standards for obtaining source documentation, applying audit standards, and providing review outcome results with relevant documentation as specified by HHS.
- **Second Validation Audit (SVA) Process.** This section provides a description of HHS' considerations on the sub-sample selection for the SVA.
- **Error Estimation.** This section provides a description of HHS'

considerations on the methodology for estimating and calculating risk score error adjustments for each issuer based on IVA and SVA findings.

- **Appeals.** This section provides a description of the ACA HHS-operated RADV appeals process, including the types of errors eligible for appeal and standards for proper submission.
- **Payment Adjustments.** This section provides an overview of how payment adjustments will be calculated and identifies assumptions made in the design of the payment transfer process and formula.
- **Oversight.** This section provides a description of HHS' considerations for standards to ensure issuer compliance with the ACA HHS-operated RADV process. The discussion will focus on the oversight process for issuers retaining an IVA entity, conducting the initial validation audit, and submitting data to HHS. This section also provides a description of some of the enforcement actions that may apply for non-compliance with data validation requirements.

HHS looks forward to receiving input from a variety of stakeholders on these sections to help inform the data validation process. Comments may be submitted by email to registrar@REGTAP.info. Stakeholders can submit their comments and upload attachments as needed and will receive an email acknowledgement that the comment was received. Comments sent in response to the paper may inform the policy development of the ACA HHS-operated RADV approach which will be formalized through regulatory and sub-regulatory guidance. Responses to the paper may be submitted by July 21, 2013.

Background

Section 1321(c) of the ACA directs states (or HHS on behalf of a state) to operate a risk adjustment program that includes all non-grandfathered plans in the individual and small group market both inside and outside of the Marketplace within a state. The primary goals of the risk adjustment program are to eliminate premium differences among plans based

solely on expectations of favorable or unfavorable risk selection, or on choices by high-risk enrollees to enroll in certain plans in the individual and small group market, and to assure that plans are not penalized for attracting enrollees with greater than average risk nor rewarded for attracting enrollees with lower than average risk. The risk adjustment program also serves to level the playing field inside and outside of the Marketplace by stabilizing premiums.

Policy parameters for the risk adjustment program are set forth in the Premium Stabilization final rule and the 2014 Final Payment Notice. Prior to issuing these two regulations:

- HHS published a white paper titled, “Risk Adjustment Implementation Issues” on September 12, 2011 (Risk Adjustment White Paper) at http://www.cms.gov/CCIIO/Resources/Files/Downloads/riskadjustment_whitepaper_web.pdf;
- HHS published a bulletin titled, “Bulletin on the Risk Adjustment Program: Proposed Operations by the Department of Health and Human Services” on May 1, 2012 (Risk Adjustment Bulletin) at http://www.cms.gov/CCIIO/Resources/Files/Downloads/ppfm-risk-adjustment_bulletin.pdf; and
- HHS held a public meeting on May 7–8, 2012 where we discussed our approach to implementing risk adjustment when HHS is operating risk adjustment on behalf of a state (Risk Adjustment Spring Meeting).

45 C.F.R. § 153.620 sets forth requirements for issuers to comply with the ACA HHS-operated RADV standards. In the preamble of the 2014 Final Payment Notice, we describe a six-stage data validation program when HHS is operating risk adjustment on behalf of a state. The data validation requirements provided in the 2014 Final Payment Notice build upon the guidance released in the Risk Adjustment Bulletin and Risk Adjustment Spring Meeting. The six stages are:

- Sample Selection;

- Initial Validation Audit (IVA);
- Second Validation Audit (SVA);
- Error Estimation;
- Appeals; and
- Payment Adjustments.

In addition, issuers of risk adjustment covered plans in states where HHS is operating the risk adjustment program are required to adhere to the six-stage ACA HHS-operated RADV process beginning with the 2014 benefit year. However, as indicated in the 2014 Final Payment Notice, we are concerned that adjusting payments and charges for health insurance plans without first gathering information on the prevalence of errors (and without a steady-state process) could lead to a costly and potentially ineffective audit program. **As a result, issuers will be required to implement a process to perform an IVA (through the use of an independent IVA entity) and HHS will implement a process to conduct an SVA for benefit years 2014 and 2015, but adjustments to payments and charges based on data validation findings will not occur for the first two years of the program.** Error rates will be estimated for each issuer. Although payments and charges will not be adjusted during the first two years, other remedies, such as prosecution under the False Claims Act, may be applicable to issuers not in compliance with the risk adjustment program requirements. More information pertaining to HHS considerations for issuer non-compliance with the ACA HHS-operated risk adjustment data validation process is provided in the Oversight section of this white paper.

HHS seeks to promote consistency and a level playing field by establishing uniform audit requirements, and to protect private information by limiting data transfers during the data validation process. We recognize the need to promote flexibility and minimize burden by allowing issuers to set their own internal deadlines for completing the initial validation audits, and to leverage existing resources to conduct data validation. As a result, we begin our discussion by seeking stakeholder input on Data Validation General Audit Standards that will apply to the IVA and SVA processes.

Data Validation General Audit Standards

45 C.F.R. § 153.630 provides the regulatory framework for the ACA HHS-operated RADV process, which includes the IVA process for each health insurance issuer of a risk adjustment covered plan to have themselves audited, and the SVA process performed by HHS. This framework applies when HHS is operating a risk adjustment program on behalf of a state. In the 2014 Final Payment Notice¹ we committed to clarifying uniform audit standards that issuers will be subject to for the data validation process, including coding and documentation standards. The following sections describe HHS' preliminary thoughts for establishing uniform audit standards for stakeholder consideration.

The purpose of these audits is to validate enrollee demographic and health status information that will be provided by issuers for HHS to calculate the individual risk scores for payment transfers. Consistent, reliable validation of enrollee demographics and health status information hinges on a uniform set of standards for the IVA and SVA. In accordance with 45 C.F.R. § 153.720(a), issuers of risk-adjustment covered plans are required to establish masked enrollee identification numbers for each enrollee. As part of the data collection requirements, HHS does not collect enrollee personally identifiable information².

Components of the audit standards defined in this section are designed to promote consistency across reviews conducted by the IVA entity and SVA entity. Since the audit standards for both audits apply to the review of demographic information, health status information, and source documentation, we organized this discussion accordingly.

¹ See page 15437 of the 2014 Final Payment Notice at <http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf>

² See 45 C.F.R. § 153.340(b)(3)

Supporting Enrollee Demographic and Health Status Information

In the preamble to the 2014 Final Payment Notice³, HHS indicated that the sample selection for data validation will include enrollees with and without risk adjustment diagnoses. For each sampled enrollee, the demographic (age and sex) and disease components (or HCCs) of the risk score will be validated. Demographics will be reviewed for all enrollees in the sample.

Health status (or disease) components of the risk score will be reviewed for all sampled enrollees with risk adjustment diagnoses based on claims or encounters submitted to the edge server. For those sampled enrollees with risk adjustment diagnoses identified based on such claims or encounter data, the risk adjustment diagnoses will be reviewed to determine accuracy of the HCC assignments.

We are considering reviewing the health status for sampled enrollees with submitted claims/encounters that have no risk adjustment diagnoses. That is we are considering reviewing available documentation for those risk adjustment-eligible claim or encounter dates of service to determine if HCC diagnoses should be assigned for risk score calculation. This would apply for both enrollees with and without HCCs.

Alternatively, for enrollees with no encounter or claims data submitted to the edge server, we are considering not permitting any records for review. This policy is being considered as a result of our general requirement that underlies our data collection process for issuers to submit claims/encounters for all services provided to enrollees during the benefit year. Therefore, we expect that all claims/encounter data submitted to an issuer's edge server for enrollees will represent the universe of service utilization in a given year.

³ See page 15437 of the 2014 Final Payment Notice at <http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf>

Documentation Review and Data Source Requirements

The documentation review will be based on the source information that could be identified as the most reliable for confirming risk score results for enrollees. This section outlines standards for documentation and data sources that will be required for enrollee risk score validation.

We expect that validation of demographic information for enrollees will be conducted through the use of issuer plan source enrollment data. This information may be in the form of enrollment transactions that take place during enrollment processes such as the 834 transaction, which is the Health Insurance Portability and Accountability Act (HIPAA) compliant form used for the plan benefit enrollment and maintenance transaction. These transactions also reflect an issuer's capturing of an enrollee's date of birth and sex demographics, and enrollment periods in each plan within the issuer.

We consider medical records for health services as the authoritative source and gold standard for documenting enrollee health status for enrollee risk scores. A medical record may include, but is not limited to, clinical documentation for hospital inpatient or outpatient treatment and professional medical treatment such as admission or discharge notes, or progress notes. We believe medical records should be used to validate enrollee health status using clinical documentation related to services that occurred during a specified period of interest (in this case the data collection period, or some point during that period) for the sampled enrollees and authenticated by the provider of services.

HHS is considering that validation of enrollee health status would be conducted through medical record review if a risk adjustment-eligible claim or encounter exists on the edge server for the sampled enrollee. For risk adjustment-eligible claims or encounters submitted to the edge server, we will define the medical record unit as the clinical documentation from the acceptable risk adjustment treating provider for the date(s) of service corresponding with the date(s) of service on the edge server claims/encounters. We will also consider any supplemental/supporting dates (outside of the claims/encounter

date(s)) only as they are acknowledged or linked by the treating provider in the medical record unit corresponding with the edge server claim/encounter. We plan to apply this approach during the initial years of the ACA HHS-operated RADV operation and may consider an alternate approach in subsequent benefit years based on our analysis of the initial years of auditing.

Diagnoses coding abstraction would be conducted in accordance with the industry standards under the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM), or the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, 4th Edition* (ICD-10-CM) guidelines for coding and reporting. These standards could be used in conjunction with industry accepted official supplemental coding clinics such as the American Hospital Association Coding Clinic⁴. We also expect that medical record review and abstraction activities should be completed by reviewers who are state certified in conducting diagnosis code abstraction in accordance with ICD-9-CM and/or ICD-10-CM guidelines for coding and reporting.

We are also exploring whether HHS should require issuers to provide evidence of original claims from which the edge server claims data were derived for the sampled enrollees. We are determining whether, or how, this information should be used as a source of evidence for services provided in conjunction with the medical record documentation.

The preamble to the 2014 Final Payment Notice⁵ describes principles for acceptable enrollment, claims, and diagnostic data for the risk adjustment models as well as data collection under the HHS-operated risk adjustment program. The ACA HHS-operated risk adjustment data validation process will follow closely with these principles for reviewing plan enrollment periods and claims diagnosis data from acceptable sources for risk adjustment. The data validation process will focus on enrollment periods and diagnosis

⁴ For more information visit www.ahacentraloffice.org

⁵ See page 15499 of the 2014 Final Payment Notice at <http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf>

services that occurred during the data collection period for payment transfers related to the specified benefit year. For example, for benefit year 2014, the enrollment periods and enrollee claims will be reviewed for dates of services that occur during calendar year 2014. We are expecting that the clinical documentation acceptable for review under the data validation process will include documentation for services provided from the following sources:

- **Hospital and Facility Sources.** Hospital inpatient, hospital outpatient, rural health clinics (RHCs), federally qualified health centers (FQHCs), or community mental health clinics (CMHCs).
- **Medical Services.** Services from sources that require a face-to-face visit with a qualified clinician. We are considering that, with the exception of tele-health services, documentation for most medical services that do not require a face-to-face visit may not be acceptable for the ACA HHS-operated risk adjustment data validation. Some examples will include documentation for such services as diagnostic radiology, durable medical equipment (DME), and pathology/laboratory. Qualified clinicians would include clinical practitioners such as a Doctor of Medicine, Physician Assistant, or Nurse Practitioner.

Developing Review Consistency and Reliability

We believe a robust data validation process should incorporate methods for establishing review processes and results consistent with the established audit standards. To accomplish these activities, the data validation review processes need to take into account formal evaluations of review activities that measure reviewer consistency within the auditing organization.

We believe requiring auditors to measure review consistency and reliability is consistent with industry standards. Such processes secure high levels of integrity on review outcomes among reviewers for similar processes. Auditors should incorporate inter-rater reliability, or inter-rater agreement evaluation into their review processes. Analyses could then be

conducted to measure the degree of agreement among reviewers, which could be used to establish certain review thresholds.

We recognize that multiple review thresholds may be necessary as some of the types of errors identified in the review process may not be comparable. One threshold we are considering is setting the minimum agreement level among reviewers at 95 percent, and that reviews are performed using rater-to-standard procedures whereby reviewers with more senior or extensive qualifications and credentials could be used to establish testing thresholds for consistency. However, we are currently evaluating whether the 95 percent threshold should be required across all components of review (demographics plus HCCs) or whether different thresholds should be established and weighted accordingly based on the types of review. For example, we could consider establishing differing thresholds, taking into account the levels of complexities that may be required to derive a given outcome, for the following:

- Percent of agreement with assigning demographic determinations for age and sex; and
- Percent of agreement with assigning HCCs.

We are also considering whether the agreement threshold(s) should be defined by a measure more rigorous than simple percent of agreement. We believe that the reviewer consistency processes would enable auditors to confirm audit outcomes and resolve discrepancies prior to making final determinations for the sample.

Confirmation of Audit Outcomes

In the event that the required source documentation (demographic and health status information) does not support the risk adjustment data submitted for risk adjustment purposes, we expect that the audits should include internal (IVA and SVA) secondary review processes to assess and adjust final audit outcomes. In this section we define some considerations for establishing uniform methods for confirming review outcomes.

Each sampled enrollee should receive one or more audit outcome dispositions based on the IVA and the SVA. The data validation outcome dispositions for each sampled enrollee should be defined by findings of no risk adjustment error or discrepancies, or findings of risk adjustment errors. We understand that across data validation audit processes different logistical errors may be identified throughout the process, many of which will have no impact on an enrollee's risk score profile. For example, if a diagnosis for an enrollee's HCC was present on a claim but not supported by medical record documentation, and a different diagnosis for the same HCC was supported by the medical record, we would define this as "no error" for the enrollee's HCC or enrollee's risk profile. However, if the medical record documentation could not support any diagnoses for the enrollee's HCCs, we would define this as an "error". For the purposes of this audit process, risk adjustment errors are determined based on changes to the enrollee's risk profile as a result of the validation audit reviews. We are also considering requiring all risk adjustment errors to be confirmed through senior level evaluation review within the auditing process prior to confirmation of error. Data validation outcome dispositions could be defined as follows:

- **No Change.** The enrollee's original risk score (prior to data validation) is equal to the risk score post data validation.
- **Risk Adjustment Error.** The enrollee's original risk score prior to data validation is not equal to the risk score post data validation. For example, an error in the enrollee's demographics or HCC status is identified after data validation review and is changed to reflect the medical record documentation. Risk adjustment error types include:
 - Incorrect demographics;
 - Original HCC was not supported by medical record review; and
 - New HCCs were identified based on medical record review.

Reasons that an original HCC may not be supported by medical record documentation may include:

- No medical record was received for the HCC, or a submitted medical record documentation did not support the HCC;

- The submitted medical record was not acceptable for risk adjustment in accordance with data collection rules (e.g., for data sources, services, and data collection period); or
- The submitted medical record was not signed by the treating provider.

In summary, HHS expects that establishing a uniform set of standards that apply to the IVA and SVA processes will strengthen the validity of the results of the audit. HHS is considering establishing guiding principles by which we will uniformly apply the general audit standards.

Data Security and Transmission Safeguards

Successful implementation of this data validation process will require proper safeguarding of enrollee information that will be transmitted between the issuers, IVA entities, and the SVA entity. HHS takes seriously the importance of safeguarding protected health information (PHI) and personally identifiable information (PII). We believe it would be necessary to define standards for safeguarding enrollee PHI and PII through proper information storage and transmission methods. Therefore, 45 C.F.R. § 153.630(f)(1)(2) requires issuers to ensure that IVA entities comply with security standards described in 45 C.F.R. § 164.308, 164.310, and 164.315 in connection with the IVA, SVA, and any appeals.

In addition to these requirements for issuers, we are also considering defining standards and expectations that would apply generally for issuers, IVA entities, and the SVA entity pertaining to data security, management, and transmission processes. Some explicit requirements could include issuer, IVA entity, and SVA entity demonstration of:

- 1) IT systems to safeguard information including encryption requirements for data “at-rest”.
- 2) IT systems to safeguard information including encryption requirements for data while in transmission.
- 3) User identity authentication and certification processes.

Similar process safeguards are currently being implemented under the MA risk adjustment data validation process, and are components of the CMS overall agency policies for authorizing systems and processes to be used for management of enrollee identifiable information for purposes of payment audits.

We will continue to explore implementation of existing federal requirements, such as those under the MA program that may be deemed necessary for ensuring proper safeguarding of enrollee PHI and PII for this process.

In summary, HHS expects that establishing a uniform set of standards that apply to the IVA and SVA processes will strengthen the validity of the results of the audit. HHS is considering establishing guiding principles by which we will uniformly apply the general audit standards.

Questions for Comment on Auditing Standards

1. Should HHS consider additional standards related to types of source information to review demographic data?
2. What additional requirements should HHS consider for documenting clinical evidence of enrollee health conditions that do not include the potential for gaming?
3. What industry best practices should HHS apply when defining a medical record as the unit for validating enrollee HCCs for a given data collection period?
4. What components should HHS consider for defining the medical record unit for review to validate enrollee health status?
5. Should HHS set a cap on the number of records an issuer could submit for a given enrollee or enrollee HCC? If so, how many records should an issuer be able to submit to support an HCC?
6. What justifications should HHS consider for allowing medical records for enrollee data that are not submitted to the edge servers?

7. Should HHS require issuers to provide evidence of original claims from which the edge server risk adjustment-eligible claims data were derived for the sampled enrollees?
8. What other considerations should be taken into account regarding the reviewer consistency requirements to assure review integrity?
9. Should issuers be allowed to submit a physician attestation for medical records that missing signatures and/or credentials?
10. Should HHS consider establishing multiple review thresholds to measure the degree of agreement among reviewers? What types of thresholds and levels complexity should be required to derive a given outcome?
11. What additional requirements should HHS consider for safeguarding data and data systems processes that include enrollee PHI and PII?

Sampling

45 C.F.R. § 153.350(a) requires that a statistically valid sample of enrollees from each issuer is validated every year. In the 2014 Payment Notice⁶, HHS finalized its plans to select the sample of enrollees for each issuer of a risk adjustment covered plan as further described in this section. These procedures will help ensure that the ACA HHS-operated RADV process reviews an adequate sample size of enrollees, so the estimated risk score errors, if any, will be statistically sound and the sample will effectively cover applicable sub-populations for each issuer. This section focuses on the sample design and calculation of the sample for the IVA.

Sampling Design

For the first year of the ACA HHS-operated RADV (the 2014 benefit year), the enrollee sample that will be selected for the IVA will include approximately 300 enrollees from each issuer to estimate a risk score error related to risk adjustment. Lower sample sizes may be calculated for issuers with a small number of enrollees (e.g., fewer than 1,000); however, the sample is not expected to be fewer than 100 enrollees for a given issuer.

⁶ p.15436 – 15437 <http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf>

To design the sampling approach for the first year of the ACA HHS-operated RADV program, HHS applied proxy sampling assumptions to error rates and population statistics as described in the following subsections. The first year will be used to gain insight on the ACA HHS-operated RADV process. As previously mentioned, no payment adjustments will be made based on the proxy sampling assumptions or their resulting error rates.

Medicare Advantage (MA) RADV net error rates and variance of net error along with Truven Health Analytics 2010 MarketScan Commercial Claims and Encounters database predicted expenditure data were used to derive principal assumptions for estimating the sample size for the program's first year, since these are the most applicable available empirical data. MA error rates were chosen since the MA program utilizes a similar HCC-based methodology to estimate risk of enrollees, and uses a RADV process to determine the payment error rates based on evaluation of enrollee risk profiles.

We used the MarketScan data because this was the primary source for calibration of the HHS risk adjustment models under the ACA. Each HHS risk adjustment model was calibrated using de-identified data from the MarketScan database for individuals aged 0-64 living in all states and enrolled in commercial health insurance plans. The database contains enrollee-specific clinical utilization, expenditures, and enrollment across inpatient, outpatient, and prescription drug services from a selection of large employers and health plans. The database also includes de-identified data from approximately 100 payers, and has more than 500 million claims from insured employees, their spouses, and dependents.

Enrollee and Issuer Population Assumptions

For the program's first year, MarketScan predicted expenditure data served as a proxy for the sampled population distribution of enrollees with HCCs. Based on the MarketScan data, we determined that approximately 20 percent of the total enrollee population will be comprised of enrollees with HCCs. In order to estimate a sample size for each issuer, we

estimated an average issuer size based on the total expected insured population and the total expected number of issuers. The average issuer population containing enrollees with and without HCCs was assumed to be split 20/80, consistent with the expected HCC/No-HCC split in the total population.

Risk Score Assumptions

For purposes of sample size calculation and risk adjustment, HHS used MarketScan expenditures as a proxy to represent financial risk. MarketScan predicted expenditure data was stratified by age group: adult, child, and infant. HHS then further stratified each age group into three risk-based strata, or thirds, based on the distribution of predicted expenditures (similar to the risk score thirds used in the MA RADV samples—see below for “Error Rate and Variance Assumptions”). Predicted expenditures were normalized and used as a proxy for risk scores, since there are no risk scores available in the MarketScan data. The expenditures were normalized to: 1) relate them to the average expenditure in each stratum by dividing by the average expenditure, and 2) uniformly adjust the ratio of two dollar values into a risk score on the similar scale to that present in the HCC Model. After year one, we will replace the proxy data with relative actuarial risk of enrollees as described in the risk adjustment model definition in 45 CFR § 153.20.

Next, HHS calculated the overall average risk score for all individuals in each risk-based stratum. This calculation was performed nine times for the HCC population, once for each of the three risk-based strata within each of the three age groups. HHS assumed the minimum risk score across all HCC strata as the risk score assumption for the No-HCC population, which was treated as one stratum. We performed a sensitivity analysis around this assumption, which is discussed in the next section.

HHS then calibrated the estimated risk scores using a linear adjustment to produce realistic risk score estimates from the MarketScan predicted expenditure data.⁷ We investigated and acknowledge the use of other non-linear adjustment methods that could be used to derive similarly reasonable risk score ranges. HHS noted that the sample size estimates are not significantly impacted by the choice of adjustment methodology.⁸

Error Rate and Variance Assumptions

The general sampling concept of the MA RADV sample includes selection of enrollees based on the health risk profile of the enrollees as determined by the source of their HCC data. Enrollees were divided into three strata, or thirds, based on the distribution of risk scores (predicted expenditures) representing low, medium, and high-risk expenditures.

For the purpose of estimating sample size, in the first year of the program, for the individual and small group markets' HCC population of enrollees within each issuer, HHS will assume the same levels of risk score error from MA error rates and variance of errors associated with the low, medium, and high-risk enrollees.

The MA RADV program only estimates error rates and variance of error rates for the three risk-related strata (low, medium, and high-risk) and does not provide any further breakout by age group. Thus, HHS will use the same risk-related stratum error rate and variance assumptions for adult, child, and infant models. For example, we will assume the adult and child HCC high-risk strata to have the same expected net error rate and variance of net error rate. We do not anticipate the expected risk score error rate and variance to be uniform for all age groups; however, this level of data will not be available for the initial year, so this will only be a first year assumption.

⁷ The risk scores discussed here are the estimated risk scores that were calculated using the MarketScan data. These risk scores are estimates of the recorded risk scores based on data that will be provided by issuers through the edge server process.

⁸ As the methodology has not been applied to any populations, the MarketScan expenditures were used as a proxy assumption until the edge server data collection process is implemented and actual data are collected. The methodology described here is only to transform the MarketScan expenditure data into realistic risk scores (i.e., numbers that are expected to be output from the risk methodology).

We also acknowledge that the MA RADV data consists of a relatively high-risk population (i.e., an elderly population of enrollees who are on Medicare with the presence of at least one HCC), and when compared to the entire population, we anticipate that this high-risk population tends to have higher error rates in risk scores and likely has higher variability in risk score errors. The risk score error rates (mean and variance) from the MA data are likely conservative estimates for the younger age groups.

For a typical issuer population, the adult strata will likely be the largest, followed by the child strata, and then by the infant strata. It is reasonable to assume that most of the enrollees in the adult and child strata will have lower risk than the MA population, and thus using MA RADV data to proxy the risk score error rate and variance is likely to be conservative (i.e., overstating what the risk score error rate and variance would be for the adult strata).

For the infant strata, there is a chance that this group may be even riskier than the MA group, and thus have a higher error rate and variance. However, the infant strata will be the smallest in size of the three age groups. Thus, we expect that a slight understatement of the risk score error rate and variance would not have a significant impact on the overall sample size calculation.

Overall, we believe the expected risk score error rate and variance assumptions, although uniform across all age groups (due to a limitation of available information), are still conservative, and therefore, the sample size calculation will also be conservative.

HHS will use the lowest error rate and variance across all HCC strata as the error rate and variance assumptions for the No-HCC stratum. Our fundamental assumption is that risk score errors in the HCC population are likely to be over-statements, meaning the HCC risk scores should be adjusted downward. With the No-HCC population, the risk score errors will likely be under-statements, meaning the No-HCC risk scores should be adjusted upward.

Given the No-HCC population will comprise the vast majority of the expected enrollee population (estimated to be approximately 80 percent of the total population), there is potential sampling risk in this population if enrollees in this stratum are misclassified as being No-HCC when they should have been included in the HCC strata (as determined after the RADV process). Consequently, there is some risk that we may be understating the error rate, variance, and risk score assumptions for the No-HCC stratum.

We performed a sensitivity analysis to determine more conservative assumptions for risk score, error rate, and variance for the No-HCC population. The resulting sampling precision for the sample sizes (discussed below) remains within an acceptable range, even under the more conservative assumptions.

Stratification

For the initial year and subsequent years when enrollee and claims data are submitted, each issuer's enrollee population will be grouped into 10 strata based on age group, risk level, and presence of HCCs. As discussed above, the basis of this stratification design comes from the MA risk thirds and the risk adjustment model age groups.

- Strata 1-3 are classified as low, medium, and high-risk adults with the presence of at least one HCC.
- Strata 4-6 are low, medium, and high-risk children with the presence of at least one HCC.
- Strata 7-9 are low, medium, and high-risk infants with the presence of at least one HCC.
- Stratum 10 will consist of the No-HCC population and will not be further stratified by age or risk level, as this stratum is assumed to have a uniformly low error rate.

The sample size will be disproportionately allocated to enrollees with HCCs (Strata 1-9) to help ensure adequate coverage over the higher risk portion of the enrollee population.

Table 1 provides a listing of assigned strata by risk level for each age group.

Table 1. Strata Mapping by Age Model and Level of Risk

HCC Stratum	Age	Risk Level	Stratum
1 or More HCC(s)	Adult	Low Risk	1
		Medium Risk	2
		High Risk	3
	Child	Low Risk	4
		Medium Risk	5
		High Risk	6
	Infant	Low Risk	7
		Medium Risk	8
		High Risk	9
No HCCs	All	N/A	10

Sample Size

For the initial year, we determined a sample size of 300 or less enrollees was adequate based on the assumptions presented above⁹. For the initial year, HHS will target a 10 percent relative sampling precision (or margin of error) at a two-sided 95 percent confidence level (CL). Thus, we wish to obtain a sample size such that 1.96^{10} multiplied by the standard error, divided by the estimated adjusted risk score, equals 10 percent or less. After actual data are collected from the initial year, we will test and evaluate the data for use in future years.

In order to calculate an adequate sample size necessary to achieve the targeted precision, we must first estimate a standard deviation of risk score error amount (S_h). For the initial year, we used the above mentioned MA RADV variance of net risk score error¹¹ assumptions. For subsequent years we will use the previous year’s actual ACA HHS-operated RADV data based on the HHS HCC RADV process.

⁹ See page 15510 of the 2014 Final Payment Notice at <http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf>

¹⁰ Critical value for the two-sided 95 percent confidence level.

¹¹ Standard deviation is equal to the square root of the variance.

We performed a sensitivity analysis by inflating the standard deviation to be conservative around the risk score estimate. An inflation factor up to three times the base standard deviation assumption was used, and still results in a precision estimate within an acceptable range.¹²

To illustrate the underlying equation, consider the following notations:

- H is the number of strata,
- N_h is the population size of the h^{th} stratum,
- Y is the adjusted risk score estimate,
- S_h represents the standard deviation of risk score error amount for the h^{th} Stratum,
- $Prec$ represents the desired precision level, and
- CI is the confidence interval associated with the desired level, that is, 1.96 for a two-sided 95 percent confidence level.

The overall sample size (n) will be calculated using the following formula:

$$n = \frac{\left(\sum_{h=1}^H N_h S_h \right)^2}{\sum_{h=1}^H N_h S_h^2 + \left(\frac{Prec \times Y}{CI} \right)^2}$$

Once the overall sample size is determined, the individual sample size per stratum (n_h) will be determined using the Neyman optimal allocation method. The Neyman allocation method calculates the optimal number to be sampled from each stratum, proportional to each stratum's contribution to the total standard deviation of the population.¹³

To illustrate the underlying equation, consider the following notations:

¹² The sample size formula can be found in Section 5.9: Cochran, William G., *Sampling Techniques, third edition, John Wiley & Sons, 1977.*

¹³ The Neyman allocation formula can be found in Section 5.5: Cochran, William G., *Sampling Techniques, third edition, John Wiley & Sons, 1977.*

- N_h is the population size of the h^{th} stratum,
- n is the overall sample size, and
- S_h represents the standard deviation of error amount for the h^{th} stratum.

The sample size for each stratum is calculated from:

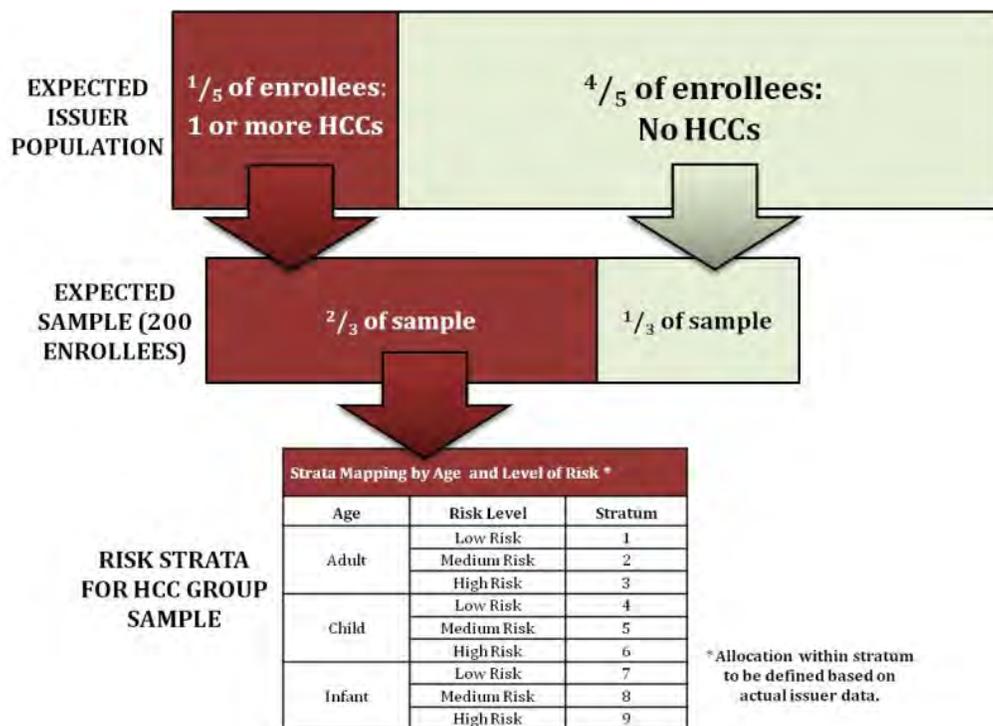
$$n_h = n \times \frac{N_h S_h}{\sum_H N_h S_h}$$

Using the above mentioned assumptions and inputs, we determined that a sample size of up to 300 enrollees is adequate to achieve the targeted precision threshold for an average-sized issuer. We also determined the same for sample sizes of 200 using the current assumptions and inputs. We note that there was a nominal change in the estimated level of precision between a sample of 200 and a sample of 300 enrollees using the current assumptions. We anticipate this finding of minimal precision difference to be similar in future years even after gathering empirical program inputs for sample size estimation. In out-years, larger sample sizes may be used for larger issuers and/or issuers with higher variability in their enrollee risk scores, whereas smaller sample sizes may be used for smaller issuers and/or issuers with lower variability in their enrollee risk scores.

HHS is also considering the use of average issuer sizes for “large” issuers, “medium” issuers, and “small” issuers based on actual data submitted for risk adjustment after the first year. All issuers will fall into one of these three sizes based on their enrollee count, and the sample sizes may be adjusted depending on the average issuer size. The sampling design may also consist of a minimum and maximum sample size per stratum for each average issuer (large, medium, small) to follow when selecting the sample.

Figure 1 provides an illustration of the population and sample distributions for the disproportionate sampling.

Figure 1. Population and Sampling Distribution Illustration Chart



Year One (2014) Sample Size Refinement—Using Actual Risk Score Data

Toward the end of the program’s first year (second half of 2014), HHS may be able to refine certain sampling assumptions with the use of actual enrollee data. The stratification design will remain consistent with nine HCC strata and one No-HCC stratum. However, the specific size and allocation of the sample size to each stratum may be refined based on average issuer enrollee risk score distributions.

Since HHS will have actual enrollee data per issuer late in year one of the program, the risk scores will no longer need to be adjusted using a linear adjustment methodology and the variance of error will no longer be based on the MA assumptions. However, the MA error rate assumptions will still be required in year one until the RADV actual error rate experience is available.

Year Two (2015) and Beyond Sampling Assumptions

For year two of data validation, we anticipate having risk score information that closely reflects the risk profile of enrollees and issuers in the ACA risk adjustment program.

Although final risk score error estimates may not be available in 2015, there will likely be sufficient sample results from the 2014 IVA/SVA process to use for the 2015 sampling plan. However, as the program progresses, we anticipate gaining experience over time that may inform comprehensive sampling processes to improve reliability of our error estimates by more effectively estimating areas of high-risk for error. We expect to improve upon the sampling process as follows:

- Preliminary results that will be available from the prior year(s) ACA HHS-operated RADV process will be used in place of the MA assumptions for expected error rates and variance assumptions.
- Actual risk score distributions from the prior year(s) or current year (if available) will be used in place of the MarketScan predicted expenditure assumptions.
- Actual issuer demographics from the prior year(s) or current year (if available) will be used in place of assumed number of enrollees and issuers.
- Sample sizes may be designed by average issuer sizes for “large”, “medium”, and “small” issuers. The sampling design could also consist of a minimum and maximum sample size per stratum for each average issuer (large, medium, small) to follow when selecting the sample.

As the program matures over time, the quality of data will improve and the sampling plan assumptions will become more reliable.

HHS welcomes comments and recommendations on the assumptions used to determine sample size for the data validation audits for the first year of the program, and for subsequent years.

Questions for Comment:

12. What level of precision should HHS seek in its ACA HHS-operated RADV processes?
13. What sample sizes are recommended to maximize the value of the ACA HHS-operated RAV process, including sound error estimation, while minimizing the burden on stakeholders?
14. Regarding the population assumptions, what other sources should CMS consider for determining sample size for measuring risk adjustment accuracy?

Initial Validation Audit (IVA)

In accordance with 45 C.F.R. § 153.630 (b), issuers in states where HHS is operating the risk adjustment program are required to engage one or more independent auditors to perform initial validation of risk adjustment data selected by HHS. The design and calculation of the sample for the IVA process was provided in the previous section of this paper.

IVA Entity Selection and Approval

The issuer must provide HHS with the IVA entity's name, qualifications, and relationship to the issuer no later than March 31 of each year, beginning in 2015. Issuers have considerable autonomy in selecting their IVA entity; however, in accordance with section 45 C.F.R. § 153.630(b), issuers must ensure that the IVA entity meets the following criteria:

The IVA entity shall be:

- Reasonably capable of performing the audit and ensuring validation of the accuracy of the risk adjustment data in accordance with HHS defined audit standards;
- Able to complete the IVA and submit IVA findings to HHS in the manner and timeframe specified by HHS; and
- Able to be reasonably free of conflicts of interest, such that it is able to conduct the IVA in an impartial manner and its impartiality is not reasonably open to question (see below for conflict of interest standards).

IVA entities may include organizations that perform independent reviews, assessments, evaluations, and analyses. They will be expected to have expertise in medical diagnosis coding and other skills necessary to evaluate the validity of risk scores. While an issuer can choose its IVA entity, the IVA entity must conduct the review in an independent manner and according to minimum audit standards established by HHS through future guidance¹⁴. In the preamble of the 2014 Final Payment Notice, we discussed three potential methods for future consideration to ensure an IVA entity meets these minimum standards. We sought input on these methods which included options for HHS approval of an IVA entity or an alternative to HHS approval. The potential options are described as follows:

- Option 1: HHS or an HHS-designated entity could prospectively certify IVA entities for initial validation audits using qualifications and credentialing requirements for performing the general audit process and complying with HHS regulatory requirements for audit quality.
- Option 2: HHS could develop standards for issuers and IVA entities to follow without a requirement of prior HHS certification or approval.
- Option 3: HHS could issue non-binding, “best practice” guidelines for issuers and IVA entities.

Although we place confidence in an issuer’s diligence in selecting IVA entities that will be capable of complying with HHS audit standards, we continue to explore the option of establishing a formal IVA entity certification or approval process for data validation in years beyond 2014 and potential barriers, including time constraints and approval/certification complexity. We have researched organizational-level auditor and plan certification processes in the Marketplace to help formulate which option would be most viable for the early years of the program. Tables 2a-2h summarize examples from our research on the certification processes, initial requirements, and the certification renewal process by the entity providing the certification or accreditation. The examples provided in Tables 2a-2h illustrate only a few organizational-level auditor or plan certification level

¹⁴ These do not represent audits under Generally Accepted Government Auditing Standards or audit standards of the American Institute of Certified Public Accountants.

processes with varying degrees of process complexity for consideration. We are seeking stakeholder input into the development of a certification process for auditors and provide some examples from our research on existing organizational-level certification process to facilitate feedback.

Some of the organizations, such as the National Committee for Quality Assurance (NCQA) Consumer Assessment of Healthcare Providers and Systems (CAHPS) and Health Outcomes Survey (HOS) vendors, are certified through a third party and contracted with health plans to perform services. Other organizations, such as the Medicare Recovery Audit Contractors (Medicare RACs), are not certified by a third party, but are selected through a request for proposal (RFP) process with their client, typically a state or federal agency, based on documented ability to perform the audits in accordance with uniform RFP specifications. The initial certification process ranges in complexity from responding to a RFP with an outline of qualifications and considered approach to a comprehensive review spanning multiple years. The level of detail required in each of these certifications also varies. Some require very little detail other than a considered plan and follow up with required training, while others require several months of surveys and on- and off-site reviews. Renewal requirements also vary in their level of rigor. Some simply require the successful completion of a webinar, while others require the applicant to essentially repeat the initial certification process. Still others have an ongoing oversight component where the contractor's work is reviewed throughout the year and considered at renewal.

Table 2a. NCQA Plan Certification/Accreditation (Source: <http://www.ncqa.org/>)

Certification Process	Initial Requirements	Renewal Process
<p><u>Application:</u> Onsite and offsite review process by physicians and managed care experts. Review includes self-evaluation and evidence of compliance with standards. Health Plans can be rated: excellent, commendable, accredited, provisional, and denied.</p> <p>Timeframe: Up to two years.</p> <p>New types of reviews in response to ACA: interim (less rigorous), first year, and renewal.</p>	<p><u>Organizations are evaluated on:</u> -Standards, an evaluation of the NCQA plan’s structure and processes to maintain and improve quality in core areas; and -Healthcare Effectiveness Data and Information set (HEDIS), and evaluation of the plan’s performance on process outcomes in clinical care and member experience of care. HEDIS/CAHPS reporting only required in years 3+.</p>	<p><u>For ACA certification:</u> -Interim certification is valid for 18 months, then move on to First Year certification. -Other certifications are valid for three years, and then must complete Renewal certification.</p>

Table 2b. NCQA CAHPS Survey Vendor (Source: <http://www.ncqa.org/>)

Certification Process	Initial Requirements	Renewal Process
<p><u>Respond to RFP:</u> Those accepted must send project director and one other individual to training.</p> <p>RFP posted every summer.</p>	<p>-Organizations must include the maximum number of surveys they are prepared to administer. -Organizations are evaluated on experience with other surveys, capacity, proposed quality control plan, background of personnel, and past performance.</p>	<p>-Certification must be renewed annually. -NCQA monitors vendor work throughout the year.</p>

Table 2c. NCQA HOS Vendor (Source: <http://www.ncqa.org/>)

Certification Process	Initial Requirements	Renewal Process
<p><u>Respond to RFP:</u> Those accepted must send project director and one other individual to training.</p>	<p>This process is open to RFP if and when the required volume exceeds current vendor capacity.</p>	<p>-Certification must be renewed annually. -Requires completion of annual training webinar. -NCQA also continually reviews work for satisfaction.</p>

Table 2d. URAC Plan Certification(Source: <https://www.urac.org/>)

Certification Process	Initial Requirements	Renewal Process
<p><u>Application:</u> Includes standards workshop, a desktop review process, and an onsite review.</p> <p><u>Timeframe:</u> Six to eight months.</p>	<p>Organizations are evaluated on a comprehensive review of organizational structure, administrative services, network management, quality management, utilization management, provider services, provider credentialing, member participation and protection, and claims processing.</p>	<p>-Certification requires monitoring onsite mid-cycle, and annual measures submission. -Certification must be renewed every three years.</p>

Table 2e. URAC Patient Centered Health Care Home Auditor Certification (PCHCH)
 (Source: <https://www.urac.org/>)

Certification Process	Initial Requirements	Renewal Process
<p><u>Attend Required Training:</u> URAC provides the certified auditor with access to tools that permit review of organization related to URAC's PCHCH Practice Standards.</p>	<p>-Certified auditors are licensed professional health care professionals who have received dedicated training in auditing of practices relative to URAC's PCHCH Practice Standards. -Certification is offered to health care organizations, health plans, and consulting companies desiring to provide independent PCHCH Practice Assessment audits to health care practices. -Uses URAC's Core Module Standards.</p>	<p>Certification must be renewed every three years.</p>

Table 2f. Medicare Recovery Audit Contractor
 (Source: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/090111RACFinSOW.pdf>)

Certification Process	Certification Process	Renewal Process
<p><u>Respond to RFP:</u> Organizations submit a bid in response to a solicitation request. A full and open competition is held by HHS to contract with these organizations.</p>	<p><u>Organization must:</u> -Demonstrate more than three years of experience of direct management experience and proficiency for cost control or recovery audits with private insurers and health care providers; -Employ registered nurses and certified coders; -Demonstrate that it has the adequate hardware and software for obtaining and storing data; and -Demonstrate a strategy to meet all timeframes and specifications regarding requesting and reviewing medical records.</p>	<p>-Contract valid for one year. -Contract can be extended up to five years total.</p>

Table 2g. Medicaid Recovery Audit Contractor (State-based: Washington)
 (Source: http://www.hca.wa.gov/documents/rfp/recovery_audit/rfp_k540.pdr)

Certification Process	Initial Requirements	Renewal Process
<p><u>Respond to RFP:</u> Organization must indicate in their mandatory Letter of Submittal that they meet or exceed all of the minimum qualifications.</p>	<p><u>Organization must:</u></p> <ul style="list-style-type: none"> -Be licensed to do business in the State of Washington or provide a commitment to attain one prior to contract execution; and -Have at least 3 years of experience providing consultation, audit, and analytical services to identify and recover overpayments made to Medicaid or Medicare providers and identify underpayments to Medicaid or Medicare providers. 	<ul style="list-style-type: none"> -Contract valid for one year. -Contract can be extended up to five years total.

Table 2h. Medicaid Recovery Audit Contractor (State-based: Alabama)

Source:

[http://www.medicaid.alabama.gov/documents/2.0 Newsroom/2.4 Procurement/2.4 RFP RAC 10-2012.pdf](http://www.medicaid.alabama.gov/documents/2.0%20Newsroom/2.4%20Procurement/2.4%20RFP%20RAC%2010-2012.pdf)

Certification Process	Initial Requirements	Renewal Process
<p><u>Respond to RFP:</u> Organization must describe, in detail, how they intend to approach the Scope of Work specified in Section II of the RFP. The ability to perform these services must be carefully documented, even if the Contractor has been or is currently participating in a Medicaid Program.</p>	<p><u>Organization must:</u></p> <ul style="list-style-type: none"> -Provide evidence that the vendor possesses the qualifications required in this RFP; -Provide a description of the vendor’s organization, including size, ownership, organizational chart, similar projects in the last three years, proposed staffing, other Medicaid entities for which vendor is currently performing work, financial statements, and details of any pertinent judgment, criminal conviction, investigation or litigation pending, and evidence of necessary licensure to be able to do business in Alabama; and -Provide three references for projects of similar size and scope. Entities that are currently excluded under federal and/or state laws from participation in Medicare/Medicaid or any state’s health care programs are prohibited from submitting bids. 	<p>Contract valid for two years, with four, one-year optional extensions.</p>

In addition to these attributes and potential certifications, an IVA entity must maintain independence from the issuer and avoid actual or implied conflicts of interest with the issuer. HHS seeks input into considering a review of an IVA entity's justification for being conflict-free before an IVA is performed. Additionally, HHS may gather information through external reporting about any relationship between an issuer and its IVA entity that may result in a conflict of interest or a potential conflict of interest. Given the complexities involved with establishing IVA entity certification processes to meet data validation requirements, we continue to explore the feasibility of such a process for reviewing potential conflicts of interest for 2014 data validation audits, and how it could be implemented.

At this stage, HHS is considering establishing minimal requirements for issuers and IVA entities to follow, and for HHS to use in evaluating the absence of conflicts of interest for the IVA process.

Criteria for assessing conflicts of interest between the issuer and the IVA could include the following standards:

- The issuer cannot have any financial interest in the IVA entity and vice versa, such that the financial success of one party could be seen as impacting the financial success of the other IVA entity team members (including senior reviewers and members of management) and their immediate families cannot have a financial interest in the issuer, including owning stock in the issuer;
- Likewise, members of the issuer's management and their immediate family members cannot have a financial interest in the IVA entity;
- Issuer directors and officers cannot serve on the board of directors of the IVA entity and vice versa;
- IVA entity team members cannot have recently been a director or officer of the issuer;
- IVA entity team members assigned to an issuer cannot be married to issuer

- directors or officers;
- The IVA entity cannot have a role in establishing relevant internal controls of the issuer related to the ACA HHS-operated RADV process or serve in any capacity as an advisor to the issuer regarding the subject matter under IVA review; and
 - The IVA entity cannot have had a role in executing the ACA HHS-operated RADV process for the issuer.

We would like to engage stakeholders on the approaches discussed in this section to help ensure the IVA entity meets the audit standards put forth by HHS.

Obtaining Source Documentation and Application of Audit Standards

For the enrollees included in the HHS selected audit sample, issuers are required to provide enrollment and medical record documentation to the IVA entity to validate the demographic and health status data of each enrollee. The issuer will be expected to work with its IVA entity to obtain source documentation from hospital and medical providers, and from the issuer's source enrollment and claims systems.

In accordance with 45 C.F.R. § 153.720(a), issuers of risk-adjustment covered plans are required to establish masked enrollee identification numbers for each enrollee. As part of the data collection requirements, HHS does not collect enrollee personally identifiable information¹⁵. As a result, since the enrollee sample will be selected based on issuer data submitted to the edge server, each issuer remains the principal source of personally identifiable information for enrollees in the data validation sample. This means that issuers hold the common association between edge server claims and enrollment data, issuer systems source claims and enrollee files, and source medical record documentation. Therefore, issuers will need to work with HHS and the IVA entity to assure that all data for the sampled enrollees are appropriately mapped to the source documentation for the enrollees in order for the initial and SVA entity to effectuate the data validation process.

¹⁵ See 45 C.F.R. § 153.340(b)(3)

This step is critical for accomplishing the data validation process since HHS does not collect personally identifiable enrollee information through the edge server. We are seeking input from issuers on best approaches for providing instructions to issuers on assuring that information for sampled enrollees are appropriately associated for the data validation process.

We expect that issuers will work with their IVA entities to obtain source documentation and relevant information that would be necessary to accomplish the validation reviews for all sampled enrollees. Only source documentation that existed for dates of services that are current during the benefit year is acceptable. This would require issuers to query their source systems to collect the appropriate enrollment and claims information. This would also require issuers to identify all claims and providers from which source medical record documentation must to be requested for review. When collecting information from hospital and medical providers, we expect that the documentation obtained for review of enrollee HCCs will be properly screened to assure accuracy with risk adjustment rules for acceptable dates of service and data sources and services in accordance with the Data Validation General Audit Standards discussed earlier. HHS also expects that the IVA entity for the issuer will meet the minimum requirements set forth under the 2014 Final Payment Notice and in future regulatory and sub-regulatory guidance.

Concept of IVA Data Validation Process and Submission of Results

Once issuers and IVA entities receive the validation audit sample from HHS, we expect the following to occur during the IVA process:

- The issuer will provide the IVA entity with enrollment and medical record documentation for the sampled enrollees;
- The issuer and IVA entity will determine a timeline and information-transfer methodology that satisfies data security requirements and enables the IVA entity to meet HHS deadlines summarized in the ACA HHS-operated RADV Implementation Timeline section of this paper;
- The IVA entity will analyze the enrollment and medical record data to

validate the demographic and health status of each enrollee in the sample in accordance with the standards outlined in the Data Validation General Audit Standards section;

- The IVA entity will be responsible for providing HHS with the final results from the IVA reviews;
- HHS will select a sub-sample of validation enrollees and request all documentation that was used in making determinations for the IVA findings for those enrollees; and
- The IVA entity will submit requested information to HHS for review.

Questions for Comment:

15. Should HHS establish an approval process for IVA entities? If so, what should that process entail? What additional information would issuers require from HHS to procure an IVA entity? In addition to medical coding expertise, what statistical or other expertise should be required of an IVA entity?
16. What other auditor qualifications should HHS consider for consistency and quality audit results, including whether a certification should be required and any expectations of that certification process?
17. What operational concerns regarding the data validation process should HHS be aware of for issuers that operate in multiple states, specifically pertaining to the need for obtaining one versus multiple IVA entities?
18. What considerations should HHS take into account regarding provider burden under the ACA HHS-operated risk adjustment data validation process?

Second Validation Audit (SVA)

In accordance with 45 C.F.R. § 153.630(c), once the IVA process concludes, the IVA entity will transmit its results to HHS for use in the SVA review. This transmission will include audit results for all enrollees reviewed and all associated enrollment and medical record

documentation for a selected sub-sample. The selected sub-sample that will be reviewed in the SVA is a subset of the sample of enrollees initially reviewed in the IVA. HHS expects to use electronic methods of submission using standardized file structures and reporting templates. We are also considering selecting the SVA sub-samples using a sampling methodology that will allow for pair-wise means testing to establish statistical difference between the IVA and SVA review results.

The SVA entity will perform the data validation review of the enrollee sub-sample following the HHS-established uniform review standards. If the pair-wise means tests result are not significant (i.e., confidence interval containing zero (0)), the IVA error rates will be used for error estimation—see the Error Estimation section for details on this test. If the confidence interval resulting from the IVA and SVA pair-wise comparison reflects significant difference (i.e., does not contain zero (0)), the SVA will take a second, larger sub-sample from the IVA results, and execute the SVA review on that second, larger sample. The second sub-sample will again be compared to the IVA sample using a pair-wise means test and again follow through the error estimation process depending on the finding of difference. If no finding of significant difference is determined from the second sub-sample, HHS will apply the IVA error rates for error estimation using all enrollees selected for IVA reviews. If a finding of significant difference is determined from the second sub-sample, HHS will derive risk score estimates based on the SVA results for the second sub-sample.

HHS is also considering ways to expedite the SVA review and appeal processes. One consideration is to start SVA reviews on enrollees for whom the IVA entity has deemed a final result prior to the end of the IVA process. In considering an expedited process, an issuer may allow its IVA entity to submit medical files and results in advance of the HHS established deadline (three to four months) for SVA submission (i.e., during the IVA review process timeframe). The SVA entity would select and review a sample of enrollees and provide feedback to the issuer on the results of that review to allow for discussions prior to finalizing the SVA findings. Similar to an appeal, this process would not allow for any

additional documentation to be submitted, but would allow for additional communications before results are finalized under the SVA reviews.

In the event HHS establishes a concurrent SVA and appeals process, we will need to develop intermediate timelines for IVA entity submission of enrollee IVA review documentation and data to the HHS SVA entity for selection of its sub-sample from each intermediate submission. Additionally, issuers that take advantage of the expedited SVA and appeals process will not be allowed to submit appeals for the same cases during the post-SVA appeals process. However, issuers may submit appeals for all other allowable cases that were not reviewed during the concurrent SVA and appeals process.

Error Estimation

HHS will estimate adjusted risk scores based on error rates uncovered in the findings from the data validation process¹⁶. Risk adjustment errors may be the result of any findings that cause a change to the demographic or health status components of an enrollee's risk score; this may include findings due to:

- Incorrect diagnosis coding;
- Invalid documentation (due to acceptable risk adjustment reasons);
- Missing or insufficient medical record documentation; or
- Incorrect determination of enrollee demographic information.

Upon completion of the initial and second validation audit reviews, HHS will derive an issuer-level point estimate of adjusted (or correct) risk score and suitable confidence interval. This estimate, or some value around this estimate will be used to adjust average plan-level risk scores for each plan offered within the issuer. HHS plans to provide each issuer with enrollee-level audit results and the error estimates. We are exploring options for establishing an estimated correct risk score, and estimated risk score error adjustment methodology at the issuer level. In this section, we describe options for calculating error

¹⁶ See page15438 of the 2014 Payment Notice at <http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf>

results based on consistency in the findings between the IVA and SVA. We also describe how the IVA sample results will be used to derive adjusted risk score estimates that can be applied to adjust average plan-level risk scores. Finally, we provide an example to illustrate the error estimation process based on those options.

Options for Correcting the IVA Results Based on the SVA Review

We are considering a two-phase procedure to accept or correct the IVA results based on the results of the SVA entity review. In Phase One, we will determine if the results of the SVA are consistent with that of the IVA. In Phase Two, we will make adjustments to the IVA results if we determine an inconsistency in findings in Phase One.

Phase One - Test of Consistency between SVA and IVA

In this phase, a pair-wise statistical test will be performed to determine if the IVA sample results should be adjusted using the results of the SVA entity review.

To illustrate the underlying statistical test, consider the following notations:

- \tilde{x}_i is the i th IVA risk score observation in the SVA sample of n observations
- \tilde{y}_i is the i th SVA risk score observation in the SVA sample of n observations
- d_i is the difference between \tilde{y}_i and \tilde{x}_i within the SVA sample
- \bar{d} is the mean of all d_i observations within the SVA sample
- S_d is standard deviation of all d_i observations within the SVA sample

A given issuer submits enrollment (demographic) and claims data to their edge server which will be used to compute risk scores (“original risk scores”). To ensure the integrity of the issuer’s data used to compute the risk scores, HHS requires that each issuer hire an independent validation auditor that reviews N enrollee records, as sampled by HHS, and validates the data for the calculated enrollee risk scores.

From the N IVA records, HHS will select a small sub-sample of n SVA records. For each SVA selected record, HHS will calculate the difference, $d_i = \tilde{y}_i - \tilde{x}_i$. HHS will then conduct a

pair-wise means test to determine whether the mean difference, \bar{d} , is statistically different than zero (0).

Specifically, HHS will test if zero (0) is contained within the bound, $\bar{d} \pm 1.96 \left(\frac{S_d}{\sqrt{n}} \right)$. If so, HHS will conclude that there is no statistically significant difference between the IVA and SVA samples and accept the results of the IVA. The IVA risk scores will then be projected to the issuer population to derive an issuer-level point estimate of adjusted risk score and suitable confidence interval – see Adjusted Risk Score Projections section below for the detailed projection procedures.

However, if zero (0) is not contained within this bound (i.e., the difference is statistically significant), HHS will expand the SVA sub-sample to select a larger subset of N , review the enrollee files, and conduct an alternate pair-wise means test using this larger SVA sub-sample. This difference may be positive or negative depending on the direction and magnitude of each difference in the SVA/IVA risk profiles. If the alternate statistical test shows no statistically significant difference, HHS will accept the results of the IVA and project the IVA sample results to the issuer populations. If the alternate statistical test shows that there is a statistically significant difference between the IVA and SVA samples, HHS will conduct Phase Two to estimate error based on the SVA findings.

Phase Two – Adjustments to the IVA Samples

We have considered two options for deriving issuer-level error adjustments under Phase Two. Option A will utilize the larger alternate SVA sample to adjust the IVA sample which will in turn be used to derive a population-based estimate of adjusted risk score. Option B will use the larger alternate SVA sample only to derive a population-based estimate of adjusted risk score.

Table 3. Adjustment Options (applied only if IVA/SVA results are statistically different)

Option	Description	Advantage	Disadvantage
Option A	Replace SVA results in IVA sample, project ratio of SVA/IVA point estimates on remaining sample, project revised IVA sample results to issuer population.	Narrower confidence interval expected based on larger sample.	May be more difficult to implement given multiple projections needed to be performed.
		Accounts for IVA findings in calculating the adjustment.	Assumes IVA error rate is uniform for non-SVA sampled enrollees.
Option B	Project SVA results to issuer population.	Single projection	Precision targets may be difficult to meet.
		Ease of execution	Wider confidence interval expected that may result in less precise adjustments.
			Disregards remainder of IVA sample findings and the associated variation.

Option A adjusts the entire sample (if there is a statistically significant difference as determined by Phase one), using a one-for-one replacement for the SVA-reviewed items and a uniform adjustment for the non-SVA reviewed items, and then projects the revised IVA sample to the universe. Option B only projects the SVA-reviewed sample items to the universe (if statistically significant differences exist under Phase one). Option B will disregard all non-SVA reviewed items. Thus, under Option A, we assume a uniform IVA error rate, and adjust non-reviewed records based on SVA results, but assume the narrower confidence interval from the larger IVA sample size. By contrast, under Option B, we simply adopt the SVA error rate, but assume the wider confidence interval from the smaller SVA sample. Whether Option A or Option B results in a greater or lesser adjustment depends upon the nature of the SVA sub-sample compared to the full IVA sample.

To illustrate the options under the Phase Two adjustment process, consider the following notations:

- M is the total number of enrollees in the sampled population (used to select the IVA sample)
- N is the IVA sample size (used to select the SVA sub-samples)
- n is the larger alternate SVA sample size
- \bar{y}_N is the mean of the IVA-adjusted risk scores in the IVA sample N
- \bar{y}_n is the mean of the SVA-adjusted risk scores in the SVA sample n
- \bar{x}_N is the mean of the original risk scores in the IVA sample N
- \bar{x}_n is the mean of the original risk scores in the SVA sample n
- X_M is the original risk score total across all M records
- \hat{Y}_N is the projected correct risk score over M using N (or “IVA Point Estimate”) ¹⁷

$$\hat{Y}_N = \frac{\bar{y}_N}{\bar{x}_N} X_M$$

- \hat{Y}_n is the projected correct risk score over M using n (or “SVA Point Estimate”) ¹⁶

$$\hat{Y}_n = \frac{\bar{y}_n}{\bar{x}_n} X_M$$

Option A: SVA Adjustments to Entire IVA Sample

Given the determination in Phase One that the results of the SVA are not consistent with that of the IVA, HHS will undertake the following steps to adjust the risk scores in the IVA samples:

- (1) Replace the IVA-adjusted risk scores with the SVA-adjusted risk scores in the n records that were sampled from N (one-for-one risk score adjustment).
- (2) Apply a uniform adjustment factor, $\frac{\hat{Y}_n}{\hat{Y}_N}$ to the IVA-adjusted risk scores in the records not reviewed by the SVA in the $(N - n)$ records.

The SVA-adjusted risk scores in all N records will then be projected to the issuer population to derive an issuer-level point estimate of adjusted risk score and suitable confidence

¹⁷] The stratified separate ratio estimator and standard error calculation is discussed in the “Adjusted Risk Score Projections” section below.

interval – see Adjusted Risk Score Projections section below for the detailed projection procedures.

Option B: SVA Adjustments to Subset of IVA Sample

Given the determination in Phase One that the results of the SVA are not consistent with the IVA results, under this option, the SVA-adjusted risk scores in just the n records will be projected to the issuer population to derive an issuer-level point estimate of adjusted risk score and suitable confidence interval. In this manner, each issuer's risk scores are corrected by the issuer's specific SVA results only.

Finalizing Risk Score Adjustments

Prior to finalizing the risk score adjustment based on the SVA findings under either of the Phase Two options, if significant differences exist in the findings, the SVA entity may request discussions with the IVA entity to identify the differences, and/or may require further review of the IVA entity's current processes. If the IVA risk score differences are substantiated, the SVA entity may adjust its risk scores accordingly. This process would not allow for any additional documentation to be submitted, but would allow for additional communications before results are finalized.

Adjusted Risk Score Projections

Based on the Phase One and Phase Two results described above, there will be one of three possible samples that will be projected to each issuer population to derive an issuer-level point estimate of adjusted risk score and suitable confidence interval.

(1) The unadjusted IVA sample N – if the Phase One test passes (shows no statistically significant difference between the IVA and SVA samples):

i. Project the mean of the IVA adjusted risk scores in N over the entire

$$\text{population M: } \hat{Y}_N = \frac{\bar{y}_N}{\bar{x}_N} X_M$$

(2) The SVA-adjusted sample N (Phase Two, Option A) – if the Phase One test fails (shows a statistically significant difference between the IVA and SVA samples).

- i. Compute the mean of the SVA-revised risk scores, \bar{y}_N for all records in N.
- ii. Project \bar{y}_N over the entire population M: $\hat{Y}_N = \frac{\bar{y}_N}{\bar{x}_N} X_M$ to arrive at the corrected total risk score for the issuer.

(3) The SVA-adjusted sample n (Phase Two, Option B) – if the Phase One test fails.

- i. Project the mean of the SVA adjusted risk scores in n over the entire population M: $\hat{Y}_n = \frac{\bar{y}_n}{\bar{x}_n} X_M$

The projections described above will be performed on a stratum-by-stratum level over the entire issuer populations to project an adjusted risk score for each issuer. A stratified separate ratio estimator¹⁸ will be used to extrapolate the total corrected risk score. To compute the stratified separate ratio estimate, HHS will first extrapolate the total correct risk score within each stratum, then sum the stratum-specific projected correct risk scores for all strata to get the overall projected correct risk score (“point estimate”). If the projected risk score error is required, it will be the recorded risk score at the issuer level minus the point estimate.

The stratified separate ratio estimator of the total correct risk score is calculated as

follows:

$$\hat{Y}_R = \sum_{h=1}^H \frac{\bar{y}_h}{\bar{x}_h} X_h$$

\hat{Y}_R is the estimate of the total correct risk score, \bar{y}_h is the sample mean of the correct risk score in stratum h , \bar{x}_h is the sample mean of the original risk score in stratum h , X_h is the total sum of the original risk score in stratum h , and H is the total number of strata.

To estimate the variance of the point estimate, HHS will first estimate the variance within each stratum and then sum the stratum-specific variances for all strata. The estimated

¹⁸ Formula and discussion on stratified separate ratio estimators and estimated variance of the stratified separate ratio estimate can be found on page 164 : Cochran, William G., *Sampling Techniques, third edition, John Wiley & Sons, 1977.*

variance¹⁸ of the stratified separate ratio estimate for the correct risk score is calculated as follows:

$$\text{Variance } (\hat{Y}_R) = \sum_{h=1}^H \left[\frac{N_h^2 \left(1 - \frac{n_h}{N_h} \right)}{n_h (n_h - 1)} \left(\sum_{i=1}^{n_h} y_{ih}^2 + \hat{R}_h^2 \sum_{i=1}^{n_h} x_{ih}^2 - 2\hat{R}_h \sum_{i=1}^{n_h} y_{ih} x_{ih} \right) \right]$$

Where n_h is the number of enrollees sampled in stratum h , N_h is the population frequency in stratum h , y_{ih} is the corrected risk score for the i th sampled enrollee in stratum h , x_{ih} is the original risk score for the i th sampled enrollee in stratum h , and

$$\hat{R}_h = \frac{\sum_{i=1}^{n_h} y_{ih}}{\sum_{i=1}^{n_h} x_{ih}}$$

the square root of the estimated variance is the standard error (SE).

HHS is considering the use of a two-sided 95 percent confidence interval to be calculated for the estimated correct risk score (or projected risk score error, as needed). Alternative intervals may be calculated for a two-sided 90 percent confidence level (consistent with HHS Office of Inspector General (OIG) standards) and two-sided 99 percent confidence level (consistent with MA RADV estimates). The two-sided 95 percent confidence interval around the corrected risk score estimate for one issuer is computed as the estimated correct risk score for the issuer (A) plus/minus (1.96 multiplied by the standard error), or (A +/- (1.96 * SE)).

HHS is considering the following options to apply an adjustment to issuer plans:

Option 1. Apply an adjustment to all plans within an issuer based on an established methodology of the ratio between the estimated average risk score and the recorded average risk score for the issuer.

Option 2. Apply adjustment based on statistical testing between the estimated and recorded risk score. Under this option, for each issuer, a statistical test of precision will be

performed to determine if the estimated average risk score and the recorded average risk score for the issuer are significantly different. Where the difference is significant, HHS will apply the established adjustment factor to all plans within the issuer. Where the difference is not significant, the estimated and recorded average risk scores are assumed to be equal; thus, HHS will not apply an adjustment factor. Under this option, HHS will need to determine whether a statistical test should be performed at the 90%, 95%, or 99% confidence level.

Once HHS has established how an adjustment will be applied, HHS will calculate an adjustment factor based on use of the point estimate, or possibly another value in the interval, inclusive of the upper and lower bound. The adjustment factor will be applied to the Plan Liability Risk Score (PLRS) in the payment transfer formula. The adjustment factor will represent the ratio of the estimated corrected average risk score (based on the data validation process) and the recorded average risk score for the issuer.

Please note that HHS intends to analyze the effects of Options 1 and 2, and the reasonableness of using the point estimate or another value within the interval based on an assessment of the impact on a given issuer.

Error Estimation Example

To illustrate the error estimation process described above, assume that a sample of 200 enrollees is selected for IVA review for a particular issuer. From this sample, assume that a sub-sample of 20 enrollees is selected for SVA review. Assume the issuer's average recorded population risk score is 1.60 and the projected correct population risk score from the sample of 200 is 1.40, with a two-sided 95 percent confidence interval of 1.30 to 1.50.

(1) The first step in the error estimation process will determine if the IVA results should be corrected based on the SVA review or accepted without adjustment.

- HHS performs a pair-wise means test to compare the difference between the sample of 200 enrollees and sub-sample of 20 enrollees.

- For this example, assume that the statistical test fails (i.e., there is a statistically significant difference between the sample of 200 and sub-sample of 20)¹⁹.
- HHS selects an expanded sub-sample of 100 enrollees from the original sample of 200 enrollees. HHS performs the pair-wise means test again, and the test fails again (i.e., there is a statistically significant difference between the sample of 200 and sub-sample of 100).
- HHS concludes that the risk scores in the sample of 200 enrollees need to be adjusted.

(2) In the second step of error estimation, HHS will employ one of two options to adjust the risk scores in the IVA sample, and then project a finalized correct risk score to the issuer's population.

Option A: adjust the risk scores in the sample of 200 using a one-for-one replacement for the SVA-reviewed items and a uniform adjustment for the non-SVA reviewed items.

- The one-for-one replacement will replace the risk scores calculated based on IVA findings with the risk scores calculated based on SVA findings for the 100 sample items that exist in the sample of 200.
- The remaining 100 items that were not included in the SVA sub-sample will be adjusted based on the ratio of two projections: (1) projected correct population risk score using the SVA findings in the sub-sample of 100 (assume this projected risk score is 1.50, with a two-sided 95 percent confidence interval of 1.30 to 1.70), divided by (2) projected correct population risk score using the IVA findings in the sample of 200 (equal to 1.40 based on the assumption noted above). The adjustment ratio is equal to $1.07 = 1.50/1.40$. So, all risk

¹⁹ If the test passes, then no adjustments will be made to the sample of 200 and the projected results from this sample will be used to adjust average plan liability risk scores.

scores in the remaining 100 items not included in the SVA sub-sample will be increased by 7 percent.

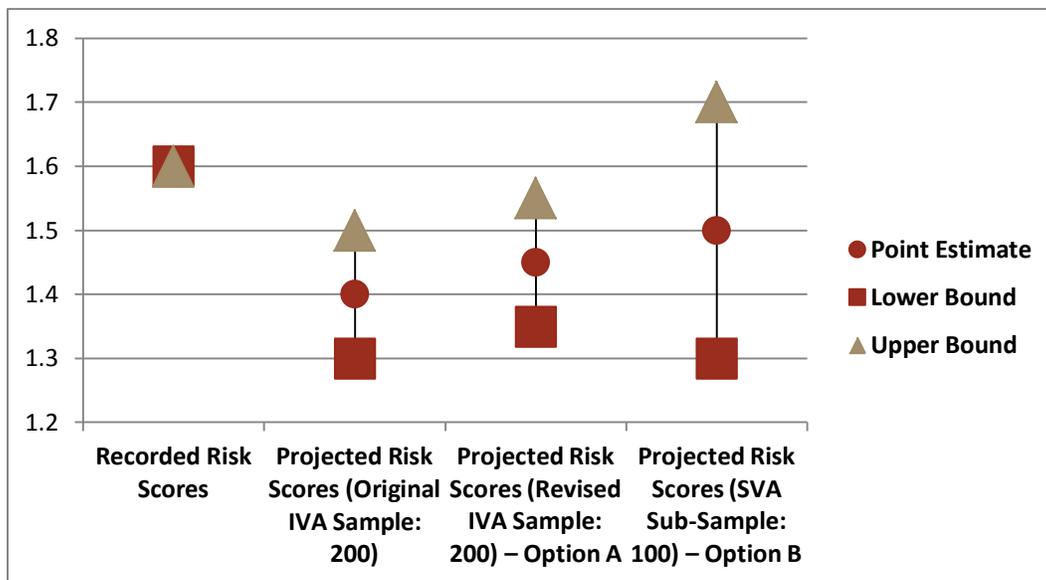
- The projected correct population risk score from the revised sample of 200 is 1.45, with a two-sided 95 percent confidence interval of 1.35 to 1.55.

Option B: projects the SVA-reviewed sample items only. Based on the example above, the projected correct population risk score from the sub-sample of 100 is 1.50, with a two-sided 95 percent confidence interval of 1.30 to 1.70.

Table 4. Summary of Error Estimation Example Results

Population Statistic	Recorded Risk Score	Point Estimate	Lower Bound	Upper Bound
Recorded Risk Score	1.60	n/a	n/a	n/a
Projected Risk Score (Original IVA Sample: 200)	n/a	1.40	1.30	1.50
Projected Risk Score (Revised IVA Sample: 200) – Option A	n/a	1.45	1.35	1.55
Projected Risk Score (SVA Sub-Sample: 100) – Option B	n/a	1.50	1.30	1.70

Figure 2: Error Estimation Example Results



Questions for Comment:

19. Should adjustments to the SVA sample size depend upon the results of the IVA entity's review?
20. If the issuer has a composite risk score significantly deviating from other issuers, should additional records be reviewed as part of the SVA entity's review?
21. What other methodologies should CMS consider for estimating the issuer-level adjusted risk score and coming up with the adjustment factor?
22. Should CMS use the point estimate of issuer-level adjusted risk score or some level (upper or lower bound) around this point estimate to derive the adjustment factor?
23. What confidence interval should CMS consider (90%, 95%, or 99%) if CMS does not use the point estimate to compute the adjustment factor?
24. What additional major concerns should CMS consider regarding measuring risk score accuracy and the impact of applying the adjustment on issuer-plans in the marketplace?

Appeals

In accordance with the Premium Stabilization final rule²⁰, HHS will establish an administrative process by which an issuer can appeal HHS' application of the data validation findings. 45 CFR § 153.630(d) allows for two types of appeals: 1. Enrollee-level Appeals - Issuers may appeal the findings of the HHS second validation audit, or 2. Error Extrapolation Application Appeals - Issuers can appeal HHS' application of the risk score error to their risk adjustment payments and charges.

Enrollee-level Appeal

The SVA entity will review issuer appeals only for the sub-sample of enrollees that were selected for SVA reviews where the SVA entity disagreed with the original risk score

²⁰ See 45 C.F.R. §153.350(d)

determinations for enrollees in the sub-sample. More specifically, we interpret this to mean that issuers may only appeal the SVA entity's decision regarding the SVA determination of an individual's diagnostic and/or demographic information that resulted in reduction of the enrollee's original risk score, or risk score element. Additionally, the SVA entity will only review documentation that was originally reviewed by the IVA entity and used as the basis for IVA entity's final risk score determination for the enrollee. That is, issuers will not be allowed to submit new documentation for enrollees during the appeals process. Issuers that choose to submit enrollee level appeals will need to provide written request to HHS for reconsideration, complete with justification for how the documentation submitted for review supports the original risk score for the enrollees. This information will be outlined in the audit report, with additional information pertaining to timelines for submission of appeals.

Error Extrapolation Application Appeal

The issuer may also appeal the application of the error rate to their risk adjustment payments and charges. In other words, if the issuer feels that the risk score error rate was applied incorrectly to the risk adjustment payments and charges, that calculation can be appealed.

The issuer may appeal if it identifies that the SVA entity did not follow the HHS data validation audit standards or payment adjustment calculation standards. The issuer may not appeal the standards of the ACA HHS-operated RADV audit itself or the payment error calculation methodology.

Appeals Process

We anticipate the appeals process will occur annually, approximately around April or May of the year that the error will be applied to the payment transfer (e.g., April 2018 to adjust 2017 payment transfers based on data validation results from the 2016 benefit year). HHS will deliver the SVA results to the issuer and IVA entity. If the audit findings are

inconsistent, issuers will have a window of time (to be determined) to file an appeal from the time the SVA results are issued.

The ACA HHS-operated RADV appeals process may follow a flow similar to an established CMS appeals processes to the extent that the ACA HHS-operated risk adjustment operational program policies and data validation processes yield similarities with other CMS programs. We are soliciting feedback on what this process should and should not entail.

Questions for Comment:

25. What is a reasonable timeframe for an organization to file an appeal once the SVA audit report is filed?
26. What elements should be required to include in the appeal?
27. Should there be a limit on the length of the appeal?
28. Should there be limited circumstances where HHS would allow additional documentation to support an appeal (for example, permitting an attestation to support a missing signature or credential on a medical record during the appeals process)?
29. What additional or different requirements should HHS consider for the issuer appeals and/or hearing process?
30. What is a reasonable turnaround time to schedule a hearing from the date an appeal was filed?
31. What is a reasonable turnaround time for appeal determinations after a hearing?
32. What characteristics of an appeal official should be considered, e.g., independence/conflict of interest requirements?
33. Should the issuer be allowed to request a different appeal official and/or an additional appeal?

Payment Transfer Adjustments

Risk adjustment payment transfer amounts will be based on error-adjusted risk scores. The data validation audits will be used to develop a risk score error adjustment for each issuer. Each issuer's risk score error adjustment will be uniformly applied to adjust plan liability risk for each risk adjustment covered plan the issuer offers. The adjustment will also be applied on a prospective basis starting with the benefit year 2016 data validation error results being applied to adjust payment transfers for 2017²¹. Each issuer's error adjusted risk scores will be calculated by dividing each enrollee's risk score by the issuer's error adjustment factor (a uniform adjustment factor will be used across all of an issuer's plans and enrollees).

Issuer's error-adjusted risk scores will need to be normalized as part of the risk adjustment payment calculation. That is the issuer's error adjusted risk scores will be divided by the market average error-adjusted risk score. As result of risk score normalization, the impact of the risk score error adjustment on risk adjustment payments or charges will depend on how each issuer's error adjustment compares to the market average error adjustment. In general, issuers with error adjustments that are higher than the state average issuer error adjustment could have normalized error-adjusted risk scores that are lower than the normalized risk scores that would be calculated in the absence of a risk score error adjustment. Similarly, issuers with error adjustments that are lower than the market average issuer error adjustment could experience an increase in their risk scores as a result of the error adjustment.

Public Reporting of Error Rates

HHS is considering reporting the following summary findings for the first two years of the program to encourage transparency:

²¹ See page 15438 of the 2014 Payment Notice at <http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf>

- Composite risk score error rates;
- Issuer error rates;
- IVA error rates; and

Projected financial impact of the proposed risk adjustment transfers. The two year period will provide IVA entities and issuers the opportunity to reform existing processes prior to the implementation of HHS payment transfer adjustments for the 2016 benefit year. As the ACA HHS-operated RADV program matures, tolerance levels may be altered in accordance with market experience pertaining to the data validation program. The industry reporting requirements considered above are intended to minimize significant differences in the risk adjustment program by encouraging market transparency.

HHS seeks input regarding considerations for reporting error rates and any additional information that could improve transparency in the markets.

ACA HHS-Operated RADV Implementation Timelines

In the preamble to the 2014 Final Payment Notice²², we stated that issuers of risk adjustment covered plans will implement the ACA HHS-operated risk adjustment data validation activities beginning with data for the 2014 benefit year. We also provided that HHS would conduct all aspects of the data validation program other than adjusting payments and charges during the first two years of the program (2014 and 2015 benefit years), including requiring the initial and second validation audits, and calculating error rates for each issuer.

For the 2014 benefit year, we expect to implement ACA HHS-operated RADV activities in early 2015. Implementation activities would begin with issuers submitting their IVA entity information to HHS for approval in accordance with 45 C.F.R. § 153.630(b)(4). In the spring of 2015, we would expect to utilize the data submitted by issuers for risk adjustment

²² See page 15436 of the 2014 Payment Notice at <http://www.gpo.gov/fdsys/pkg/FR-2013-03-11/pdf/2013-04902.pdf>

payment and charges and apply the sampling methodology identified in the 2014 Final Payment Notice to select and distribute the audit sample to issuers for the initial validation audit. During the same timeframe, we expect to train issuers and IVA entities on the ACA HHS-operated RADV process and the applicable standards for performing the IVA which begins in the summer 2015. Once the IVA process has concluded in the fall, HHS will begin the SVA process which continues into 2016. The ACA HHS-operated RADV implementation activities for the 2014 benefit year data conclude in 2016 after distribution of HHS findings to issuers, appeals are processed, and final risk scores are estimated and reported. Since the 2014 benefit year is the first year of the ACA HHS-operated RADV implementation, we expect to report on lessons learned from these activities and use this information to improve the ACA HHS-operated RADV process where appropriate.

We expect that the ACA HHS-operated RADV implementation activities would follow the same schedule for each subsequent benefit year with the exception of reporting lessons learned each year. The 2016 benefit year would be the first year when payments are adjusted and occur after the conclusion of the ACA HHS-operated RADV activities for the 2016 benefit year in June 2018.

Oversight

Issuers, IVA entities, and the SVA entity must comply with the ACA HHS-operated RADV requirements set forth in the Premium Stabilization final rule and 2014 Final Payment Notice and codified at 45 C.F.R. § 153.620 and 153.630. HHS will provide oversight of the ACA HHS-operated RADV audit process, including taking certain actions in cases where issuers and/or their IVA entity are not following these requirements. The compliance actions associated with each requirement are discussed below.

Reporting Information on the IVA Entity

If the IVA entity's name and information is not provided to HHS in accordance with HHS requirements for reporting and timeframes, we will follow up with the issuer. We may

provide assistance, as needed, to the issuer in identifying appropriate validation audit firms or types of validation firms.

Before engaging an IVA entity, the issuer is expected to verify and document that any key individuals involved in supervising or performing the initial validation audit have not been excluded from working with either the Medicare or Medicaid program. We may elect to review the IVA entity's qualifications and the determination that there are no conflicts of interest in the event issuers have not met this requirement. This could include using external sources to assess potential conflicts of interest and certifying that the IVA entity has the knowledge, skills, and abilities to conduct a high quality IVA that meets industry standards and HHS requirements. Any problems or potential problems noted by HHS in reviewing the IVA entity information submitted by the issuer or that otherwise comes to our attention will be made known to the issuer.

If an issuer does not hire an IVA entity, HHS will not perform the IVA function for issuers. Instead, we are considering assigning the issuer a default error rate. The default error rate would be based on the highest possible value for the error rate that guarantees additional charges as a percentage of the premium or reduced payments as a percentage of the premium. We are considering developing a methodology for computing the default error rate, including examples of applying the methodology in future guidance. We are also considering that a data validation default error rate could also be applied in cases where analysis of an issuer's error results are suggestive of problematic issuer data submitted to the edge server by issuers and/or suggestive of problematic application of the general audit standards by the IVA entity.

Issuers that do not hire an IVA entity by May 31 of each year (or two months after certification in instances where HHS elects to certify the IVA entity), beginning with 2015, or hire an IVA entity having a conflict of interest, will be subject to civil money penalties (CMPs). Section 1321(c) of the Affordable Care Act states that the provisions of section 2736(b) of the Public Health Service Act (PHS), which refers to CMPs, shall apply to the

enforcement of risk adjustment. The maximum amount of penalty imposed under section 2736(b) is \$100 for each day, for each individual, with respect to when such a failure occurs. In addition to continuing daily civil monetary penalties, HHS may refer the issuer for possible enforcement action.

Conducting the IVA

As discussed earlier, IVAs must be conducted in accordance with HHS requirements, which are based on industry standards for risk adjustment validation. The suggested timeline for the data validation process indicates completion of the IVA process and delivery of IVA findings to HHS no later than November 30 of each year, beginning with 2015. We will monitor and follow up with any issuers for which complete and timely IVA reports are not received to determine the reasons for any delays and whether the IVA was even performed.

For late reports, issuers would be subject to CMPs under section 2736(b) of PHS beginning the day after the audit report is due to HHS, or December 1 of each year. If HHS has not received a validation audit report within one month of the due date, it will apply a default error rate to the issuer as previously described.

Data Submission for SVA

Issuers and IVA entities must comply with requests for information and otherwise cooperate with respect to the enrollee sub-sample selected by HHS for the SVA. We will monitor and follow up when required information, such as sub-sample enrollee information, is not submitted timely or completely. As needed, we will provide technical assistance to the issuer and/or the IVA entity to resolve any problems.

We may refer the issuer and/or IVA entity for possible enforcement action if necessary data to perform the SVA is not provided, or if the issuer or IVA entity has an unusual error rate that is later found by the SVA entity to be materially unreliable.

HHS will specify the manner for transmitting and the timeframe for submitting risk adjustment data and source documentation needed to perform an SVA. Issuers and IVA entities must comply with HIPAA privacy and security standards. HHS will monitor HIPAA data privacy and security through complaints from stakeholders and will raise with issuers and IVA entities any observations and concerns so that immediate corrective actions can be taken. We will refer the issuer and/or the IVA entity to the normal HIPAA privacy and security compliance process if there are any potential HIPAA violations or compliance issues.

Receiving Technical Assistance

HHS will offer technical assistance as needed and promote an environment of open communication with the issuers and IVA entities. There may be new or emerging issues or concepts that need clarification with issuers and IVA entities. We will use a range of communications tools, including: additional guidance, training materials, webinars, and user group calls.

Issuers may request technical assistance at any stage of the process, or we may initiate it if we become aware of problems. We envision ongoing communication with industry stakeholders about challenges, best practices, and possible solutions. For example, we could help the issuer explore (1) why it may have trouble with data submission; (2) what its IVA results mean, especially where the results indicate the issuer is an outlier; and (3) the type of actions needed to mitigate any problems identified by the IVA entity or SVA entity.

Referral for Possible Follow-up for Compliance and Fraud Enforcement

If there are any findings, by the IVA entity that HHS' fraud surveillance and oversight activities find to be suggestive of potential fraud, we will refer issuers to the appropriate Federal fraud enforcement entity. Behaviors that might warrant such enforcement referral may include: (1) IVA entity findings that indicate significant

problems in risk adjustment calculations, (2) an issuer that does not conduct an IVA, or (3) an issuer or IVA entity that does not submit necessary data to HHS for the SVA. We welcome input on HHS oversight considerations for data validation.

Questions for Comment:

34. What thoughts do you have with respect to HHS' plans and criteria that should be used to compute and assign a default error rate in instances where an IVA is not performed or is performed by an IVA entity having a conflict of interest or if the IVA report is not timely submitted to HHS?
35. What other oversight considerations should HHS consider to promote confidence in risk adjustment transfers in the Marketplace?

Conclusion

Although we have provided the regulatory framework for the ACA HHS-operated RADV in the Premium Stabilization final rule and 2014 Final Payment Notice, many of the detailed processes within this framework have yet to be specified, as discussed in this white paper. We look forward to receiving comments on those processes that have yet to be specified via email to registrar@REGTAP.info by July 21, 2013. We will be evaluating the options raised in this white paper along with comments submitted to finalize the ACA HHS-operated risk adjustment data validation process.